UNIVERSITY OF MICHIGAN

Multifunctional Labor and Delivery Device

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APPENDIX 1

TABLE OF CONTENTS

I. EXECUTIVE SUMMARY

This past summer, our team spent four weeks conducting clinical observations at Komfo Anokye Teaching Hospital (KATH) in Kumasi, Ghana. We co-identified challenges with staff in order to determine aspects of maternal health which could benefit from design innovation. During this expereince we identified a disconnect in the system between labor and delivery. Based on our observations, we identified a need to design a streamlined, multifunctional labor and delivery device to be used in resource-limited settings, such that patients may labor and deliver in the same location, thereby increasing the safety, comfort, and efficiency of the birthing process for mothers, infants, and birthing attendants. While at KATH, our team interviewed doctors, nurse-midwives, and medical students in the Obstetrics and Gynecology (Ob/Gyn) department in order to obtain user requirements for our design project. Using open ended questions and surveys, we constructed a ranked order of user requirements and translated each requirement into engineering specifications.

Upon returning to the States we interviewed University of Michigan Ob/Gyns (Frank Anderson, M.D, and Jason Bell, M.D, M.P.H.) and others knowledgeable in Ghanaian culture and practice (Joseph Perosky) in order to adjust and fine tune our user requirements. Upon updating our user requirements we began brainstorming design concepts. We started by individually brainstorming full concepts. From this exercise we came up with eleven full concepts. Based off of the full concepts, we then broke down features of the concepts by function. We continued brainstorming as a group and added additional mechanisms under each function based off of inspiration we derived from seeing our teammate's designs. We then discussed the advantages and disadvantages of each mechanism for each user requirement. Based on price, feasibility, practicality, cultural acceptability, and likelihood of mechanisms being used, we selected one mechanism under each user requirement to incorporate into our alpha design. At this point in time we contacted our Ghanaian mentors, Dr. Odio, and Dr. Djokoto and provided them with a detailed report of the design as well as pictures for feedback.

Since the alpha design, our project has continued to evolve to better meet the needs of our target audience. Upon meeting with Dr. Anderson we reworked our adjustable height, leg support, and access to pelvis mechanisms. Additionally we researched materials and cost to further refine our design to meet the $500 USD budget we received for this course. We have performed extensive engineering analysis to justify the safety and practicality of our device given our design. Working within the constraints of this undergraduate design course, our team had 4 weeks to manufacture our design. Thus, our prototype to date has many of the features our ideal device would contain, but there exists many components of the bed which will benefit from further design iterations in the upcoming semester. Upon completing the manufacturing of our prototype our team performed initial validation to assess some of the key user requirements. Next semester we will focus our efforts on redesigning features of the device which did not meet the specifications of our user –requirements. Further, we will travel to Ghana with a scaled down version of our device to obtain feedback regarding the cultural appropriateness of our device. While in country we will also spend time assessing the local materials available. This information obtained will be influential in the redesign of our device. Currently we are working with business analysts to assess the viability of implementing our device on the global market. This paper provides documentation of the design process in its entirety. In this paper we have recorded the methodologies employed for obtaining user requirements and engineering specifications as well as strategies used for concept generation and selection. We discuss the design manufacturing plans, final prototype, and how this design differs from our ideal device. We will also explore the challenges faced at various phases of the design process, and how those challenges were dealt with. We will conclude by providing our thoughts on what we could have done differently, and what we plan to do in the future with this device.

II. INTRODUCTION / BACKGROUND

The following section provides a comprehensive background description of our project. We begin with our problem description which details our observations in the hospital in Ghana. We then briefly discuss our potential market, the influence of culture and history on childbirth, U.S. hospital and FDA regulations on obstetric beds, anthropomorphic data, and benchmarking relevant to this project.

PROBLEM DESCRIPTION

The Labor and Delivery ward at KATH is overcrowded and under-supplied. On average there are 26 spontaneous vaginal deliveries a day, and only 9 labor beds and 2 delivery beds to accommodate such births. Beds are shared among patients and the delivery beds are only to be occupied once women present 10 cm dilated. The lack of space and inadequate number of labor and delivery beds in the ward resigns many women to laboring in the hallway or on the floor. Frequently patients do not make it to a delivery bed to deliver, and skilled birth attendants are not always prepared to birth babies throughout the ward. Our clinical observations and interviews with numerous skilled birth attendants helped us to identify several challenges in the current model of childbirth at KATH. These challenges are surely not unique to KATH but are shared among developing nations which suffer from the same constraints leaving their hospitals and clinics overpopulated and under-supplied. The result is compromised maternal health delivery, and poorer outcomes.

Our primary concern with the current model of childbirth at KATH is the unnecessary transfer of patients from labor to delivery beds at a physically and emotionally crucial state of labor. This transition places mothers and infants at increased risk of contracting diseases as bodily fluid are lost and exchanged, and increases the likelihood of suffering from adverse delivery outcomes. Additionally, the current system increases congestion and chaos in the labor and delivery ward by continuously transferring patients between beds. It is an inefficient use of resources as multiple persons per bed increases the amount of waste and time necessary for cleaning of equipment.

The design of the current labor and delivery beds are another major concern of ours as their static and uncomfortable arrangement inhibit optimal positioning of mothers and birthing attendants. As patients vary in size, they frequently must contort their bodies to properly fit in the delivery beds. This creates additional stress and discomfort for patients, thereby increasing the strain of the birthing process. Increased pain from uncomfortable positioning may even increase duration of delivery.

Women deserve to deliver in safe and comfortable conditions, and our team seeks to contribute to Millennium Development Goal (MDG) 5 by improving the conditions in which women deliver universally. Our project goal is to design a streamlined, multifunctional device to be used in limited resource settings, such that patients may labor and delivery in the same location, thereby increasing the safety and comfort of the birthing process for mothers, infants, and birthing attendants.

KATH indicated a strong desire for a device to improve the birthing conditions of women at their hospital. The Head of the Department of Ob/Gyn, Dr. Anthony Odoi, was particularly supportive of this project. He will serve as our local sponsor and consultant throughout the design process. Locally, Dr. Frank Anderson, and Dr. Jason Bell Department of Ob/Gyn at University of Michigan Hospital have offered to serve as consultants. Their work and knowledge in global health will provide an additional valuable perspective throughout the design process.

Figure1: Delivery Station at KATH[i]

DATA ON NUMBER OF BIRTHS IN AFRICA

The total fertility rate represents the average number of births a woman has in her lifetime. The total fertility rates in African nations are among the highest worldwide. Throughout Africa the majority of nations reported total fertility rates ranging from 3.56 (Ghana) to 7.75 (Niger).[ii] Such data indicates that childbirth, and child-birthing practices may have profound health implications on the women of these societies as they spend a large portion of their lives pregnant! Just as gender and culture influence women's health outcomes, so does geography. Where a woman lives, and what health facilities and trained attendants she has access to could be a matter of life or death if and when pregnancy complications arise. Women living in rural areas are more than 2.5 times more likely than women living in urban areas to suffer from maternal mortality. Though not all deaths in rural settings can be attributed to the lack of a skilled birth attendant, a study evaluating the effects of obstetric service access on maternal mortality outcomes in West Africa indicated that the large disparities between rural and urban maternal health outcomes is correlated to access to high quality maternity care.[iii] In urban settings the vast majority of births (83%) occurred in a health facility or with a skilled provider (69%). However in rural settings 80% of women gave birth at home without any skilled care.[iv] To use Ghana as a model, it is estimated that in Ghana, over 530,000 births occur annually.[v] The urban/rural population distribution in Ghana is 43.8%/56.2%.[vi] If we discount the fact that women living in urban environment likely have less children on average than their rural counterparts due to increased education and socio-economic status, it can be roughly estimated that the number of births that occur in a health facility in Ghana is around 252, 916 annually. Said another way, it can be estimated that nearly half (47.7%) of the births in Ghana currently occur in a health facility.

530,000 (births annually) x 0.44 (population living in urban regions) x 0.83 (births in a health facility of those living in urban regions) = ***193,556 births per year in health facilities in urban Ghana***

530,000 (births annually) x 0.56 (population living in rural regions) x 0.20 (births in a health facility of those living in rural regions) = ***59,360 births per year in health facilities in rural Ghana***

In Ghana, the average number of hospital beds per 1000 people is 1.5.[vii] However, the quality and functionality of such beds included in this statistic is questionable. Based on the number of births which occur annually, 252,916 and the scarcity of beds, it is likely Ghana's health, in particular Ghana's maternal health outcomes could improve by increasing the number of hospital beds. For comparative purposes, Monaco, a nation with one of the lowest maternal mortality ratios, has nearly 20 beds per 1000 people.[viii]

SAFE MOTHERHOOD AND HUMAN RIGHTS

In 2000, the United Nations (UN) adopted the Millennium Development Goals (MDGs) as a concerted effort to address significant social, gender, and health disparities around the world. The fifth MDG aspires to diminish the negative effect of gender on women's reproductive health by improving maternal health. In 2005, over 500,000 women died due to pregnancy or pregnancy related complications and of those over 95% occurred in Southeast Asia and Africa.[ix] This suggests that the social construction of gender in these nations creates an undue burden for women as reproductive health and rights are disproportionately denied to these women.[x] MDG 5 has expressed its intention to reduce gender health disparities by reducing maternal mortality 75% between 1990 and 2015, and achieving universal access to reproductive health services by 2015.[xi] However, data presented in 2009 at the UN conference on maternal mortality reductions were disheartening, as hardly any measurable decreases were reported.[xii] It is worthwhile to consider that high rates of maternal mortality are a violation of human rights in the following areas:

- Rights related to life, liberty, and security of the person
- Rights related to the foundation of families
- Rights related to equality and nondiscrimination on grounds such as sex
- Rights related to the highest attainable standard of health, and the benefits of scientific progress

This human rights framework may be useful as the "re-characterization of maternal mortality from a health disadvantage to a social injustice may place governments under legal obligation to remedy the injustice."[xiii]

CHILDBIRTH AND CULTURE

Culture, a set of beliefs, customs, and values shared between groups of people at a given period in time, is significant to women's health. Though culture is dynamic and continuously evolving, many rituals and practices are cherished and remain constant over generations. One such ritual which varies by culture but has profound implications on maternal health is childbirth. The following paragraphs will compare variations in birthing practices across cultures, while evaluating the maternal health outcomes associated with each.

DEVELOPING NATIONS

Zambia: Cultural practices in Zambia suggest that myths, spirits, and "medicines," play a significant role in childbirth. Sickness during pregnancy indicates the mother and fetus are in a spiritually weak state and must be protected from wickedness. Local medicines are administered to pregnant women six months prior to labor and right before labor to prepare and widen the birth canal. When a woman is in labor, she is typically supported by 3-4 women, all of whom are family except perhaps the *mbusa* who serves as a traditional birth attendant (TBA). *While in labor women may choose whichever birthing position they desire, such as squatting or kneeling. However a typical position includes the mother sitting with her*

buttocks resting on a pressure ring of chitenge (a fabric Zambian women use to tie around the waist) placed on top of the mat. Other women sit behind her to give her support. Whichever the woman's choice, seclusion is of the utmost importance, preferably in huts. Crying during labor and delivery is not allowed, and it believed to cause still-birth.[xiv]
Zambia ranks 8th in the world among countries with the highest maternal mortality ratios. (650 per 100,000 live births)[xv]

India: The community norm in the rural city of Rajastan prefers home births to hospital births. Women believe TBAs are knowledgeable and that hospitals cause disease and poorer health outcomes. Further, women enjoy the hands-on-approach, and touch that TBAs provide throughout the birthing process. However women are not generally the decision makers in this culture and it is the pregnant woman's father or husband that decides where she will give birth. *In both hospital and home birth settings women generally labor and deliver in a bed.* This allows for easy access to the pelvis to assess labor progress, as well as allows for birthing attendants to provide fundal pressure during delivery when necessary.[xvi]
India ranks 18th in the world among countries with the highest maternal mortality ratios. (550 per 100,000 live births)[xvii]

Bangladesh: The following expert from an ethnographic study of birthing practices in Bangladesh illustrates the cultural aspects of birth in this nation:

> "*Mrs. X lay flat on the floor covered by a jute mat* and the TBA massaged her abdomen with mustard oil in an attempt to push the fetus downwards. At the same time the mother-in-law gave specially treated water bani pora) to her daughter-in-law to drink in order to accelerate the labor. This water bani pora) was blown upon by the TBA. The TBA then mixed mustard oil and plain water and rubbed this inside the woman's vagina with her bare left index finger. At that time Mrs. X was crying loudly. When the TBA removed her index finger it was coated in blood. The TBA then made the woman kneel with her legs apart as her mother-in-law sat in front to offer support. The TBA sat behind the woman and instructed her to push down harder. After about ten minutes Mrs. X cried very loudly as the head of the baby became visible. The TBA caught the baby between her hands with a piece of cloth and delivered the child."[xviii]

Bangladesh ranks 34th in the world among countries with the highest maternal mortality ratios. (350 per 100,000 live births)[xix]

Though somewhat variant, the birthing practices in these different cultures share similarities in 1) who is present at birth, i.e. traditional birth attendants and other women, 2) myths and rituals surrounding childbirth, 3) unconventional "medicines" to assist in the birthing process, and 4) overall high rates of poor maternal health outcomes. The variations in birthing positions among these nations indicate birthing positions are culturally symbolic, not medically superior. In sum, their cultural practices suggest that culture does influence women's health outcomes as the acceptance or rejection of trained skilled birthing attendants, and scientific medicine and practices are all culturally influenced.

HISTORICAL PERSPECTIVE, WESTERN NATIONS

The evolution of popular birthing positions in Western nations has been largely influenced by cultural advancements, particularly in the field of medicine. Before forceps and anesthetics were introduced to the birthing scene women commonly labored and delivered standing up, in squatting positions, on hands and knees, or side lying. However, as the field of obstetrics advanced and became more surgically oriented in Western nations, the need for physicians to have direct and immediate access to the pelvis drove the popularity, and now almost universal practice of laboring and delivering lying down.[xx] The lithotomy

position is frequently criticized by feminists as it is believed to take agency and power away from women during the birthing process and place it in the domain of the physician. Feminists argue women should be active participants in the birthing process and this position inhibits women from participating fully by restraining her ability to labor in the position she is most comfortable. The lithotomy position has no scientifically proven advantage in reducing the pain or time associated with labor when compared to other birthing position. Its primary "advantage" is that it makes labor and delivery more comfortable for health care attendants by providing easy access to the birth canal. Though relatively few studies have been performed evaluating the advantages of different birthing positions on maternal health outcomes, data thus far does not provide strong evidence that there is in fact a "best" birthing position. Therefore, when choosing birth positions, the most important consideration should be patient preference.[xxi]
United States ranks 116th in the world among countries with the highest maternal mortality ratios. (8 per 100,000 live births)[xxii]

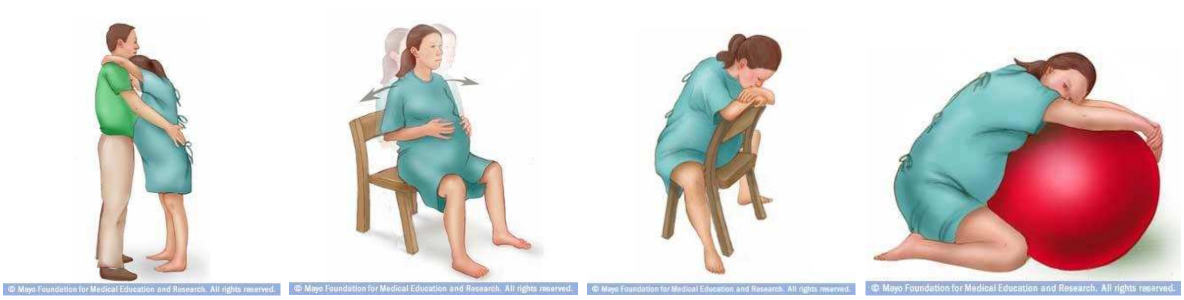
PROGRESSION OF LABOR AND DELIVERY

The labor process can be categorized into four distinct phases: dilation, pushing, placenta, and bonding/recovery. The first phase can also be broken down into the latent, active, and transition stages. During the first phase of labor the cervix dilates from 0-10 cm. The average length of time for this process to occur for a first baby is 12-14 hrs. The second stage of labor consists of pushing the baby through the birth canal. This can take up to 2 hours for a first baby! The third stage of labor involves the birth of the placenta and typically takes less than thirty minutes to complete. It is imperative during this stage to ensure all products of conception are removed from the uterus, as the uterus is rapidly contracting and any products left behind can lead to serious infection or post-partum hemorrhage. The final stage of labor involves emotional and social aspects of childbirth such as bonding and stabilization of mom and newborn.[xxiii] Based on this data it can be expected that first time mothers may spend up to 17 hours in a hospital bed laboring and delivering! Increasing patient comfort during this period is surely important then as women experience pain and discomfort for a long duration.

LABOR AND DELIVERY POSITIONS

The pictures below illustrate eight common positions in which women may labor and deliver. These include: standing, swaying back and forth, sitting backwards on a chair, using a birthing ball, squatting, semi-recumbent, hands and knees, and laying sideways. [xxiv]

Figure 2: Labor Positions[xxv]



DESCRIPTION OF US HOSPITAL REGULATIONS OF LABOR AND DELIVERY

All hospitals in the United States much comply with The Occupational Safety and Health Administration (OSHA) which guarantees safe working conditions to both public and private workers.[xxvi] That being said, the American Public Health Association has issued guidelines for the regulations of birthing centers which ensure that births which occur outside of hospitals in birthing centers are as safe as possible. In their regulations they do not make any specific regulations regarding labor and delivery beds, nor the number of patients/skilled birth attendant or patient/area. However, they indicate the facility should be "equipped with those items necessary to facilitate s low-risk birth."[xxvii]

DESCRIPTION OF FDA REGULATIONS OF HOSPTIAL BEDS

An obstetric table and accessories is classified by the FDA as a class II medical device.[xxviii] However a manually adjusted hospital bed is classified as a class I medical device.[xxix] Class II devices are more tightly regulated than class I devices and may require special labeling, mandatory performance standard, and post market surveillance as they have the potential to cause injury or harm to patient users.[xxx] Risk of entrapment has been identified as the greatest risk of the obstetric bed and the FDA has special guidelines to prevent this from occurring. However, it is worth noting that FDA guidance does not establish legally enforceable responsibilities.[xxxi] In the guidelines which articulate how to reduce the risk of entrapment it recommends minimizing gaps and spaces between bed parts, and reducing the number of accessories put on and taken off the bed. Additional attention must be paid to the area of the bed where the head lies and the position of railings as these areas place the patient at most risk for becoming entrapped in the bed.[xxxii]

ANTHROPOMORPHIC DATA

Anthropometry refers to the measurement of the human individuals. Locating anthropomorphic data for an African population has been extremely challenging and time intensive. Initially we were using anthropometric data from the 1990's but more recently we have collected anthropometric data from 2005 published by the Center for Disease Control (CDC). This new data breaks down anthropomorphic measurements by race, however we were wary about assuming that African American demographics were the same as African demographics. Another useful resource our team located was the text *Woodson Human factors Design Handbook* (1997).[xxxiii] This text provided comprehensive data regarding different human body measurements, however the data is somewhat out of date. Our team is concerned that we have not been able to locate data from an African population, but we believe by using data from the U.S. as a benchmark, and also comparing this data to the measurements of current hospital beds on the market, we feel comfortable that this information will help us to create a bed appropriately sized for our target market.

Recently our team has also contacted the coordinator of library global initiatives at the University of Michigan, Gurpreet Rana, and she suggested searching Gender Info 2007, UN Data, World Bank Open Data, Pub Med, and Google Scholar. We performed a search using key words such as "anthropometric data," "human body measurements," "body sizes," "anthropometrics," and "female body measurements." Aside from the minimal data from the early 1990's and the non-comprehensive data provided from the CDC we have still been to date unsuccessful in finding good, credible data regarding anthropometric measurements of African women. It is our goal by DR 4 to have these nailed down. Recently Preet has indicated her frustration as well as a librarian at being unable to find a relevant data set and has indicated she will continue to look and ask her global health colleagues if they could direct her and us in a more useful direction. Though our population is growing and a more recent data set would be valuable, below are two somewhat useful tables we have located thus far describing female body measurements:

Figure 3. Anthropomorphic Data of African American Population[xxxiv] (CDC, 2005)

	Percentiles		
	5th	50th	95th
standing height	60.2 "	64.2"	68.4"
weight	117.2lbs	174.9lbs	278.7lbs
upper leg length	34.9cm	40.5cm	45.7cm
waist circumference	72.1cm	96.6cm	126.6cm
mid-arm circumference	25.6cm	33.3cm	45.6cm
max calf circumference	32.3cm	38.8cm	48.6cm
mid-thigh circumference	45.1cm	57.1cm	74.1cm

Figure 4. Anthropomorphic Data of American Female Industrial Population[xxxv]

Anthropometry of industrial populations 375

Table 1C. Industrial anthropometry for female industrial population measured by OSU Biodynamics Lab (1984–1991).

	Female population (125 subjects)		Percentiles		
	Mean	(SD)	5th	50th	95th
AGE	39·74	(10·44)	25·0	39·0	58·0
WEIGHT (lb)*	142·24	(25·92)	105·0	141·5	195·0
HEIGHT (cm)*	163·71	(6·21)	153·4	163·5	174·3
SHD HT*	135·40	(5·95)	126·0	135·0	145·0
ELB HT*	102·34	(4·52)	95·1	102·0	109·8
UARM LGT	33·28	(1·92)	30·4	33·0	36·9
LARM LGT	43·69	(2·83)	40·3	43·6	49·0
TRK LGT	50·64	(3·37)	44·6	50·5	56·5
AB BRDTH*	28·06	(3·69)	22·6	27·8	35·2
AB DPTH*	21·84	(4·30)	15·7	21·6	30·0
AB CRC*	82·64	(12·11)	67·2	81·0	105·0
LEG LGT*	88·25	(4·83)	80·7	87·9	95·5
LLEG LGT*	45·05	(3·18)	40·3	44·7	50·0

*Measured with subjects wearing light clothing and shoes.

CURRENT TECHNOLOGIES AND INNOVATIONS

The devices mentioned in this section represent the wide spectrum of labor and delivery devices available today. These technologies were found using patent searches, obstetric journals, visiting hospitals in Ghana and India and videos of women delivering in various cultures.

Through our market research we benchmarked a wide range of technologies including obstetric tables for hospitals, home birthing equipment, and add on accessories that aid in the birthing process. For the hospital settings, we found multifunctional obstetric devices that covered a broad range of the cost spectrum. On the expensive end we benchmarked the Huntleigh BirthRight Delivery Bed that cost nearly $25,000USD. [xxxvi] We found that this bed had mechanisms to address the functional user requirements that we generated. This included mechanisms for back support through inclinable back, height adjustability, leg separation using stirrups and retractable lower one-third of the bed for access to pelvis. On the contrary the bed was priced at more than 25 times our requirement and hence is not feasible for the developing setting. Having sophisticated electrical controls is another disadvantage since electrical power supply might not be consistent and the electronic circuitry can be difficult to repair by the local technicians. On the other end of the spectrum was the Obstetrics Table by A.M. Technologies[xxxvii] priced at approximately $1,000USD. Although this table is relatively inexpensive, it is designed primarily for delivery purposes and lacks the comfort we desire for long periods of labor[xxxviii]. Among other issues, it has straps for leg separation and does not have an adjustable height.

Apart from these two technologies, there are hundreds of similar beds manufactured by different companies around the world. However there is no evidence of any low cost solution that addresses all the requirements we have listed. Another alternative we considered to the labor and delivery bed was add-on accessories. In this category we found an "OB/GYN backpack" made by a Rice student team for portable diagnostic purposes[xxxix]. The leg separation device in this kit is innovative but lacks rigidity to serve as firm delivery equipment.

From a non-traditional approach, we found a few devices that enable delivery in chair like and hanging positions. [xl] Although innovative, these devices are still at the development level and haven't made it to the market yet. Also, from our observations in Ghana we can safely say that changing birthing procedures and practices can be very difficult in places where a particular method has been followed for many years. The non-traditional approaches call for a significant change in procedures and we can foresee difficulty with wide scale implementation of such devices. Listed below are different kinds of technologies available in the market related to the birthing process. This is not a comprehensive list of companies and products since a lot of similar devices are made by various companies. Table1 is a benchmarking table we have made for leg separation and Table 2 is a benchmarking table of other full concept designs signifying the wide spectrum of products on the market. The technologies below have been divided into three parts: bed like, non bed-like, and accessories.

Current Technologies:

Bed Like:

- *Huntleigh Birthright Bed Dilivery Bed*
  http://www.arjohuntleigh.com/int/Product.asp?PageNumber=&Product_Id=253
- *Obstetrics Labor Table*, A M Technologies, India
  http://www.amtechindia.com/obstetrictable.html
- Labor Delivery and Patient Care bed, Fenick US4,139,917
- *AFFINITY 4 BIRTHING BED*, Hill Room
  http://www.hill-rom.com/usa/Affinity.htm
- *Delivery Bed*
  http://www.hospital-furniture.co.in/delivery-bed.html

- Ave New Generation Birthing Bed
  http://www.newstylehealthcareservices.co.uk/index.php?id=products&section_id=8&category_id=20&product_id=39

- *S.S Delivery bed-G8686VJ*, China
  http://www.anbochina.com/examination+bed-china/examination+bed-S.S+Delivery+bed-G8686VJ-167/

Non Bed-like:

- United States Patent US4221370
- New Design of Obstetric Delivery Bed for Alternative Births (09 CZ 0747 3DSS)
  http://www.technology-market.eu/medimap/Profiles/09_CZ_0747_3DSS.html
- *Birth pools*, Waterbirth International
  http://www.waterbirth.org/mc/page.do?sitePageId=45760&orgId=wi

Accessories:

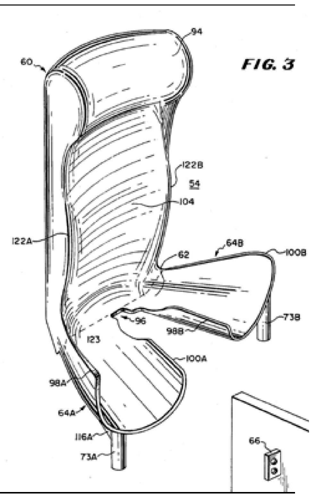
- *OB/GYN Backpack ,* Rice University
  http://www.rice360.rice.edu/content.aspx?id=675
- *Action Candy Cane Stirrup Covers and Foot Pad*
  http://www.allegromedical.com/patient-care-c530/candy-cane-stirrup-pads-padded-stirrups-pr-p210687.html

Table 1: Technologies for Leg Separation [xli],[xlii],[xliii],[xliv]




Type	Back of knee	Strap	Portable Stirrups	Footpad (in white)
+	*Provides the most control over the pt.	*Simple design *Not in the way, does not extend outside of bed frame	*Accessory: could be added to existing beds *Inexpensive (in theory no actually data exists)	*Force disturbed over larger surface area that other devices *Maintains pt. dignity by allowing woman to control leg separation
-	*Complex design *Diminishes pt. dignity as legs pt. loses all control	*Difficult to sustain large force *Would require overhead bar to hand them from	*Made of wood, would not have long lifetime, would become contaminated quickly *Unknown how much force it would sustain without breaking *Not currently available on the market	*Less control over pt. than traditional stirrups *Sticks out of the bed frame: potentially gets in the way of traffic

Table 2: Technologies for the labor and delivery process

Benchmarks			
Price	~$25,000 USD	~$1000 USD	Patent
Source	Huntleigh BirthRight Delivery Bed	A. M. TECHNOLOGIES	United States Patent US4221370
Height	30-33” Adjustable	31.5” Not Adjustable	Adjustable
Width	36”	35.4”	28”
Back Angle	0-70°	0-45°	Vertical but Adjustable
Pelvic Access	1/3 Drops away	1/3 Slides away	Leg Separation
Leg Separation	Calf Supporters	Leg Straps	Thigh Pads and Stirrups
Fluid Collection	Rectangle Bin	Cut-Out	None
Safety	Side Railing, 180kg	Side Railings	Back Contour
Easy to Clean	Yes	Yes	Yes
IV Stand	Yes	Yes	No

III. PROJECT REQUIREMENTS AND ENGINEERING SPECIFICATIONS

We determined our user requirements from interviews conducted during the month of August at KATH with various stakeholders, as well as through literature reviews on labor and delivery beds in clinical and scholarly articles. Physicians, residents, nurse-midwives and nursing students were questioned as to what features were most important and desirable to a multifunctional labor and delivery device. Current technologies were referenced within the interviewing process as a tool to acquire specifications for user requirements. After a large number (16) of user requirements were gathered, a preliminary survey with user requirements (Appendix A, Fig.A1) was distributed to 30 staff members within the Ob/Gyn department. Each user requirement was ranked on a scale from 1-5 (1= least important, 5= most important). Additionally we left room for further suggestions. After initial evaluation of data collected from the first survey, the exact preference of certain user requirements was unclear. Thus we created a second survey (Appendix

A, Fig.A2) which was given out in which we asked participants to rank seven user requirements 1-7 (1=most important, 7=least important). These surveys helped enable us to rank the user requirement in order of importance based on the preferences of staff at KATH. Throughout the Fall 2010 semester our user requirement list has remained dynamic as we have gathered additional information from local mentors and literature.

Below are the user requirements and engineering specifications generated by our team from the stakeholder feedback in descending order of importance. The red line on the table below signifies the division between what we have determined to be must-haves vs. luxuries. The features above the line represent a non-negotiable requirement for implementation, i.e. safety regulations and economic restraints. Alternatively they represent basic features/functions the labor and delivery device must possess as indicated by the staff, given the time and space constraints of limited resource hospitals and clinics. Features that fell below the line were either not directly necessary for the facilitation of a safe delivery, accessories, or features of a bed not frequently utilized by patients or birthing attendants. After discussions with local mentors our rank order changed from the order presented in the first design review. Namely safety was increased to the number one requirement for both ethical and legal reasons described below. Back inclination was increased over adjustable height as the former is more significant to patient comfort whereas the latter is more significant to provider comfort. Last, we increased longevity as data suggests more than half of medical devices in limited resources settings are not currently in use although the vast majority of these devices could be fixed with limited skills.[xlv] Therefore it is critical that our device has a long lifetime as broken equipment is hardly ever repaired.

Table 3: Rank order listing of user requirements and engineering specifications

Rank	User Requirements	Engineering Specifications
1	Safe • Static Load	 289kg with X_{sf} =2
2	Inexpensive	<$1,000 USD
3	Quick & Easy to Adjust	≤3 steps or ≤30 s requiring ≤22lbs force
4	Adjustable Lumbar Support	0-70 ° from horizontal
5	Adjustable Vertical Height	25” to 38” from floor
6	Leg Separation/ Access to Pelvis	30-45° from the body’s bilateral plane of symmetry ≤27.8” distance from pts pelvis to health care attendant
7	Long Lifetime • Bed frame material • Minimal Maintenance • Hold up to cleaning agents	≥5 years
8	Patient Comfort/ Mattress • Mattress Softness • Width	 Thickness 5”, foam, pressure reducing Width >30”
9	Fluid collection system	>6 L, ≥12”diameter

10	Quick to Clean	1-5min,
11	Easy to repair	Machine-able by in-house BME staff person using locally available material: i.e. steel, aluminum, wood, rubber, iron, rods, within a day Mechanical not Electrical
12	Anti-Corrosive Mattress Cover	Stain and corrosion resistant material
13	IV stand	44.5”
14	Pelvis Inclination	±15° from the horizontal
15	Railings	13.25” from mattress 35” length
16	Container for supplies/charts	12”x4”x8” / 9.5” x 13”
17	Leverage for patient hands	≤27.8” from head end of device
18	Light Source for suturing	>60 Watts
19	Transportable	≤88lbs

ENGINEERING SPECIFICATIONS

1. Safe

Originally number 10 on our user requirement list, after discussions with Joseph Perosky and Dr. Sienko we moved safety up to the number one priority on our user requirement list. We discussed the ethical implications of an unsafe device and determined it would be irresponsible and unethical of us to create a potentially unsafe device for the public to use. Additionally we made this decision for legal reasons as the FDA has strict regulations regarding the safety of this class II medical device with which we must comply.[xlvi] Further, Patients should feel secure when using the equipment within the hospital. A safety factor for all loads should be at least 2, to protect against unexpected loads or misuse.[xlvii] Based off preliminary static load analysis, the device should be able to support up to 191kg. (126.6kg *95% Weight* x 2 *safety factor) + (18kg upper limit gained during pregnancy x 2 safety factor*[xlviii]*)* = 289kg (636lbs).

2. Inexpensive

A low cost device was the first concern on the minds of our stakeholders. If the cost is too high to order the number of beds needed, the problem of having only a few delivery stations will continue. According to our interview with Dr. Odoi and the business manager, the estimated cost should be $2,000 or less per device. Dr. Odoi also mentioned if the price is below $2000, smaller hospitals and private clinics would be better able to purchase this device as well.[xlix] As many hospitals throughout Africa are under-equipped, especially with hospital beds, a labor and delivery device which is inexpensive while providing safety and support to patients would surely increase the quality of care patients’ experience.[l] In Ghana, the Ministry of Health owns over 70% of all hospital beds.[li] Thus, as the government is the probable buyer of the product, and it recently purchased (2) $25,000 beds for KATH, we believe $2000 is an appropriate target price and would make our device affordable in bulk for the country of Ghana, and countries with the similar economic profiles. This would likely increase the low hospital bed to person ratio which currently exists (1.5 beds/ 1000persons).[lii] This may then lead to more women delivering in health care facilities. As women that deliver in healthcare facilities have lower rates of maternal mortality and morbidity than those that do not, purchasing more hospital beds may indirectly reduce the maternal mortality ratio.[liii] Recently upon meeting with Dr. Kibatala, a practicing physician in Tanzania we became aware the even within developing nations there are variations among hospital spending. Dr. Kibatala indicated that Ghana is a "rich" country, so spending $2,000 USD on a hospital bed may be appropriate, however in Tanzania, they do not have that sort of funding available and a $1,000 USD price would be more attainable given their buying power. Therefore, it will be necessary to perform a cost analysis to determine if reducing the price to $1,000 UDS will increase our market drastically enough to support this cost reduction. Our business associate Alice Zheng is currently looking into hospital spending reports/records to help further support this number as a reasonable price for our medical device. A "Market Assessment Outline Plan" is included in Appendix B and indicates the sort of parameters Alice will be looking into. We will provide answers to many of the outlined questions by DR 4 and those not assessed by that point in time will be researched more fully next semester.

3. Quick and Easy to Adjust

If the transition from labor bed to delivery bed is not quick and easy to perform, the staff will not convert the labor beds to delivery beds. Though the delivery beds at KATH have the potential to be adjusted, because it was too difficult, the delivery beds remained in the same position for all women. On average, there were 6-11 staff members per shift in labor and delivery. This included nurse managers, midwives, cleaning staff and errand runners. Because the patient to attendant ratio is high, the staff needs to be able to use their time efficiently. Midwives and nurses were interviewed to determine the time and sequence and number of steps to transform a bed. The time they estimated as acceptable for adjusting the bed was less than 60 seconds (maximum) with (≤3) steps using 22lbs of force.[liv] Anthropomorphic data on reasonable weight limits for occasional lifting for women ranges from 22-33lbs.[lv] Our observations suggest that 60 seconds appears to be too much time and we did not witness tasks requiring this much personal attention being completed. Therefore our observations suggest that less than 30 seconds for the reconfiguration is a time limit that would suffice. As no current data exists which demonstrates allocated time per patient for staff members, we have to use our limited observations as the basis for this time value. As the current amount of time necessary to transport a woman from a labor bed to a delivery bed varies by each individual woman, we measured the transport time to be between 1 and 5 minutes depending on when you start recording time (once woman is trying to get herself up, once woman is off the bed, once she has reached the delivery bed, once she is properly positioned, etc. etc.) By eliminating this transfer time healthcare attendants will be able to service women exactly when they are needed, and not be delayed due to movement of women across the ward.

4. Adjustable Lumbar Support

The labor beds are completely flat for women to rest or sleep comfortably while in labor. For the delivery, the midwives would prefer to raise the back of the women so she is in a comfortable position to push. The angle range suggested was 0-70 degrees; this was obtained from both interview and literature.[lvi] The length of the back segment was measured from current delivery beds in usage from two different labor wards, A1 and A5, to be 27" to 40". Anthropomorphic data of women measures the trunk between 17.39" to 22" (5-95%).[lvii] Thus we must design a back support at least a 22" trunk in order to accommodate 95% of the population. However we recognize this data is not comprehensive of African populations, thus we will continue to seek to validate this measurement.

5. Adjustable Vertical Height

It is important during labor that women may get on and off the bed as they please to move around. Further, it is important the bed is positioned such that medical staff can examine the woman regularly to assess labor progress. When checking the dilation of the cervix, the physician often sits on the side of the bed next to the patient. When it is time to deliver, the midwife or physician generally stands in front of the woman's pelvis. Thus there are different heights which must be considered when designing a labor and delivery device.

Labor Height: Anthropomorphic data on leg length suggests women's leg length varies for the most part from 31.7"-37.6" (5-95%).[lviii] Therefore our bed should not exceed 31.7" at base-height as anything higher would be difficult for a woman to get on unaided. Ideally the device should be at least 6" shorter than 31.7" (25.7") such that a woman may easily sit on the bed without straining herself.

Delivery Height: Because most midwives prefer to stand while delivering a baby, the labor/delivery bed should be able to adjust upwards such that the woman's pelvis is in line with a standing midwife's waist. Using anthropomorphic data gathered on women's leg length, the bed should adjust to 31.7"-37.6" (5-95%) above the floor level to accommodate most midwives height.[lix]

6. Leg Separation/ Access to Pelvis

The midwives at KATH showed and mentioned a strong preference for stirrups over foot rests because they have better access to the woman's pelvis during the delivery, and they provide more stability for the patient. However, legs placed in stirrups too long can lead to a condition known as peroneal nerve palsy, a mononeuropathy of the lower extremity.[lx]

The stirrups currently are set at one position: a height of 10.5" from the mattress. The planar rotation of the stirrup pad was ~45 degrees from the centerline of the patient. The radius of curvature of the padding was ~2" to conform to the calf. The overall length of the calf padding ranged from 11.5"-13.5" and the width of the ranged from 5.5"-8". These dimensions are all specific to stirrups, but we do not want to constrain our design to this specific feature. Alternatively we observed that many women grip the back of their thighs and pull their legs back while delivering, suggesting stirrups or a formal leg separation device may not in fact be necessary to incorporate into our design. When we met with Dr. Anderson he showed us a video of a woman giving birth in Haiti on a deliver bed that had vertical poles extending outwards from the end of the bed which she placed her feet on while pushing.[lxi]

Using anthropomorphic data, women's leg length varies for the most part from 31.7"-37.6" (5-95%).[lxii] Their lower leg varies from 15.8-19.6" (5-95%).[lxiii] Therefore it can be deduced the upper leg varies from 15.9-18" (5-95%). If we design a leg separator in which the woman's knee fits into it should not be more than 15.9" from the end of the bed while delivering. If we design a foot support it should not be further than 31.7" from the end of the bed to accommodate 95% of the population. A benchmaking table of existing leg separation devices demonstrates current devices on the market used to separate legs (Background Section, Table1*).

In addition to separating legs, birth attendants need proper access to the pelvis during the delivery for the safety of the infant and mother. This is a key step in the conversion from the laboring stage to delivering stage as the section of the device in which the legs rest during labor will likely need removed when it is time to deliver. Anthropomorphic data on the range of women's arm length suggest most women's arms range from 27.8"-33.8" (5-95%).[lxiv] Therefore the device should not inhibit the attendant any more than 27.8" from the pelvis of the patient.

7. Long Lifetime

More than 50% of laboratory and medical equipment in resource-limited settings is not in service.[lxv]However, the data suggest that it is possible to return the majority of this equipment back to service using only a minimal skill set.[lxvi] This is important to our design as fear of selecting materials that could break only to never be replaced has been an important factor in our materials selection. For instance, we are considering a hydraulic pumps to adjust the height of the bed, however if it broke, the adjustable height feature of our bed may be lost. This data lends us to believe the majority of failures which occur in medical devices could be fixed locally given minimal education. Given this information, the lifetime of our bed greatly varies more so on the education of local technicians, and less on the presence of locally available materials. As we witnessed most "broken" material does not get fixed, it would behoove us to design a device which has a long lifetime.

That being said, our interviews at KATH suggested that ≥ 5 years was the minimum acceptable lifetime. This estimate includes the regular 3 month maintenance plan for small repairs needed while still in use. We plan to calculate and test our design through a theoretical cyclic failure analysis.

8. Patient Comfort/Mattress

Our interview with birthing attendants informed us that patient comfort is largely related to adequate back support and having enough area on the mattress to adjust positioning. Mattress tension was about hard to medium compared to mattresses in the US, and the overall width of the bed should be ≥30". Comparing two mattresses, the staff preferred a softer mattress for the comfort of their patients but a tough plastic-canvas covering for easier cleaning and increased durability. The preferred mattress was a 5" thick hard foam mattress. Patient comfort for KATH staff meant a soft sturdy mattress. Our mattress will be at least 68.5" tall, but likely longer as we recognize the population studied to gather this anthropomorphic data may not represent the African population accurately.[lxvii] Additionally we recognize there is a need for hospital beds which may support the full spectrum of women laboring, including populations of women with larger girth. This will be challenging for us to develop a design which does not harm women with smaller frames, but provides adequate support for women with larger bodies. In order to accomplish this we may have to include two options for various features such as stirrups.

Quantifying "comfort" has been challenging for us. One way in which we can increase patient comfort is by attaining a pressure reducing foam mattress. Additionally we are selecting a foam mattress over a spring mattress to more evenly distribute the patient's weight. A foam mattress will also allow us to cut the mattress into the different pieces we will need given the adjustability of our bed. Another way we will assure the mattress is comfortable is by asking volunteers to sit on the bed and rate the comfort on a scale of (1-5), 1= not comfortable, 5= very comfortable. Based on volunteer's responses on the survey we will validate whether or not our mattress is comfortable. For our purposes we are seeking scores greater than or equal to 3 (comfortable).

9. Fluid Collection

Collecting fluids during delivery is a critical step in keeping the labor ward clean and preventing the spread of disease. In a typical vaginal birth, the volume of blood lost should be less than 500ml.[lxviii] Additionally, amniotic fluid, urine, and other water and products of conception exit the vagina. Therefore, it will be necessary for a bucket or collecting system of sort to hold all this material. After taking measurements after vaginal births at KATH of the volume of material deposited in the bucket, it was determined that a minimum volume of 6L is necessary to collect all fluids and debris. We observed two different collecting systems, one with a circular diameter of 12"on the floor, the other a horizontal rectangular shaped bin directly under the woman's pelvis. The large circular container was preferred for collecting fluids as it was perceived to catch a greater proportion of waste. Because the circular bin is their current practice, they were resistant to changing their behavior to a rectangular bin. Thus we will likely use a circular collecting system in our design. Last, the material of the container should be a hard plastic for cleaning ease.

10. Quick to Clean

The current cleaning process in limited resource settings involves a harsh bleach cleaning agent which takes 10min to be disinfect disease spreading microbes. Beds are cleaned between patients, thus with high turnover rates, the quicker the beds can be cleaned, the sooner another woman can have access to a bed. We observed the time necessary for cleaning beds and it ranged from 1-5min to complete the process. When speaking to Dr. Anderson he mentioned the ability to clean the bed quickly as very important, and suggested we cut down on the number of crevices or creases in the design to minimize exposed surface area which will need cleaned.[lxix] He shared with us experiences of his in limited-resource settings and explained that beds with gaps in the joints frequently get blood stuck in them. The material which covers the mattress should be stain resistant and capable of retaining its integrity throughout frequent cleanings with corrosive materials.

11. Easy to Repair

It is estimated that of the non-working medical devices in low-resource settings, over 60% could be repaired with locally available material if repair personal had the minimal requisite knowledge necessary to make such repairs.[lxx] In order to increase the likelihood our device will be able to be repaired if something breaks we are making a device which is mechanical, rather than electrical in nature. For efficiency purposes the frame of our bed will likely be made of all the same material. We will look into high carbon steel with a stainless coating because this material stands up better to their disinfectant Parazone, and will not corrode. When surveying the local markets, we found wood, plastics, sheet metal of aluminum, rubber, and other miscellaneous items. We will therefore try to incorporate these materials into our design.

12. Anticorrosive Mattress Cover
Anti-corrosive materials should be selected to maintain an adequate lifetime for the device as strong cleaning agents (Parazone) are used to disinfect against HIV and other diseases. This will likely be some sort of vinyl material.

13. IV Stand
An IV stand was mentioned as being necessary to the bed because of the medications that are administered during the labor and delivery process. Dimensions were taken from the current stand in use, set at the height staff preferred to use. Height of IV rod is 44.5" from the bottom of the mattress and it is placed on the right side of the bed. Many stand alone IV stands exist however so we do not believe it is imperative to incorporate an IV stand into our design.

14. *Pelvic Inclination*
Ob/Gyn doctors mentioned that there should be some way to tilt the pelvis for easier access. Orientation would depend on need such as delivering or sewing up lacerations, but the range should be from ±15 degrees from horizontal. This measurement was gathered from Dr. Anthony Odoi, Head of the Department of Ob/Gyn at KATH.[lxxi] However we have been unable to find data to support this angle of inclination. Subsequent discussions with Ob/Gyn physicians in the U.S. have not indicated an inclined pelvis is necessary or preferred for delivery.[lxxii] Therefore we will not have a pelvis inclination function present on our device.

15. Railings
Railings is a safety feature we are considering to keep patients from falling out of the bed. Measurements of the railings were taken from a new delivery bed which staff said were in the appropriate location. The height from the mattress to the top of the railing was 13.25" with a length of 35". However, upon conducting research on obstetric beds, we learned through reports from the FDA that bed railings have the potential to cause entrapment of patients.[lxxiii] This is potentially dangerous and thus must be considered if incorporating railings into our design.

16. *Container for Medical Supplies/Charts*
Organization of medical charts is important for reference and monitoring of patients during labor and delivery, especially when computer and electrical monitoring and not taking place. We thought it would be useful to have a place to store the medical charts of patients such that physicians and nurses could locate medical records quickly and easily. Upon measuring the charts at KATH we determined a slot for charts measure 9.5" by 13". A drawer to hold a small delivery kit so every delivery station had the requisite tools necessary for delivery would measure around 12"x4"x8" in volume.

17. *Leverage for Patient Hands*
While delivering we observed many women holding on to the mattress or their thighs. However, we did observe that some women used handles to grip while pushing. If we included handles on the bed, based on anthropomorphic data of women's arm length, 27.8"-33.8" (5-95%)[lxxiv] any overhead hand grip should not extend more than 27.8" from the back of the mattress.

18. *Light Source*
Lamps and/or a light source are helpful for birth attendants after delivery when any suturing of lacerations occurs. Therefore a lamp that could come out from the bed would benefit the staff while performing these tasks. The lamp should be at least 60 Watts.

19. *Transportable*
From our observations the labor and delivery beds were never moved from the ward. If patients were transferred from the labor ward to the surgical theater this was done by a trolley. Therefore, we do not feel it is necessary that the labor and delivery device be extremely mobile. However, in other settings it may be necessary that the bed be mobile and transfer the patient from the labor ward to a surgical theater. Therefore we have not eliminated the option of a transportable device. Also, the device should not be so heavy that the bed could not be delivered to the labor ward in the first place. Anthropomorphic data on reasonable weight limits for occasional lifting for women range from 22-33lbs.[lxxv] The device should not be heavier than four women can lift, therefore we will aim to create a bed less than 88lb.

QUALITY FUNCTION DEPLOYMENT
After constructing our list of user requirements and engineering specifications our team decided to use a Quality Function Deployment (QFD) to display the interactions between these two lists. While creating the QFD, our team was forced to analyze every aspect of our design specification more in depth by asking ourselves what was truly important to each component. The QFD also helped us to see connections between engineering specifications that depend on each other. Through the QFD we recognized the dependence of adjustability on the different features such as back inclination, optimal height, leg separation and access to pelvis. We also saw that cost and longevity are linked together and might have to be balanced against each other. Increasing the longevity of our device will affect the cost. The process of making the QFD allowed our team to organize our thoughts into one set of ranked engineering specifications. During the design process, our QFD will be referenced to keep our focus on what is important. The QFD clearly outlined the relationships between our specifications and requirement for us to critically analyze our design parameters. Our QFD diagram can be found in Appendix C.

IV. CONCEPT GENERATION
The entire procedure of concept generation was an iterative, multi-approach process. The major approaches that were used were conceptualizing whole solutions, using functional decomposition to identify key functions our bed must provide, component brainstorming as a team, and brainstorming as a class. Through the use of these techniques, we were able to generate about 60 single and multi-functional concepts. These concepts were brainstormed without any restriction regarding whether or not they were feasible.

A particular challenge we found after our early brainstorming was trying to “think outside the box” and generate intuitively non-feasible concepts. We would immediately disregard these ideas instead of sharing and allowing them to inspire other thoughts, therefore we had to actively allow ourselves to think without restrictions. Also, when brainstorming together we had to work to not judge each other’s concepts and to keep an open mind when discussing ideas.

Upon completion of our initial individually bed “whole concept” brainstorming session , concepts generated were divided into two categories: traditional and non-traditional devices. Traditional devices are those which are more bed-like, similar to those commonly found in hospital and clinical settings. Non-traditional devices are those that are either uncommon or completely novel ideas. After dividing the concepts into these categories we broke down all of the concepts by the different functions these devices performed.

INITIAL BRAINSTORMING

For the initial attempt at concept generation, each member of the group separately came up with full concepts. These concepts included some but not necessarily all of the components described on our user requirements list. A full list of these concepts can be found in Appendix D. We chose to generate concepts individually so that each person would have the opportunity to explore generating both traditional and non-traditional birthing concepts. In all we came up with 11 of these whole system concepts which include an egg pod, table, inflatable reconfigurable bed, pyramid mechanism device, reconfigurable foot table, crib recliner, roller, features as attachable and removable accessories, a traditional bed recliner, a hammock, and rocker. A few of these will be described in detail below.

FUNCTION DECOMPOSITION

Next, we created a functional decomposition chart, (Table 4) to organize and determine all the functions that our device should perform. Through the functional decomposition we are able to follow the flow of information, materials and energy through our system. We identified the major steps our device will go through during the birthing process. Within the four major steps, we determined several sub functions under each and connected them by the flow of material, information and energy.

Table 4: Functional Decomposition

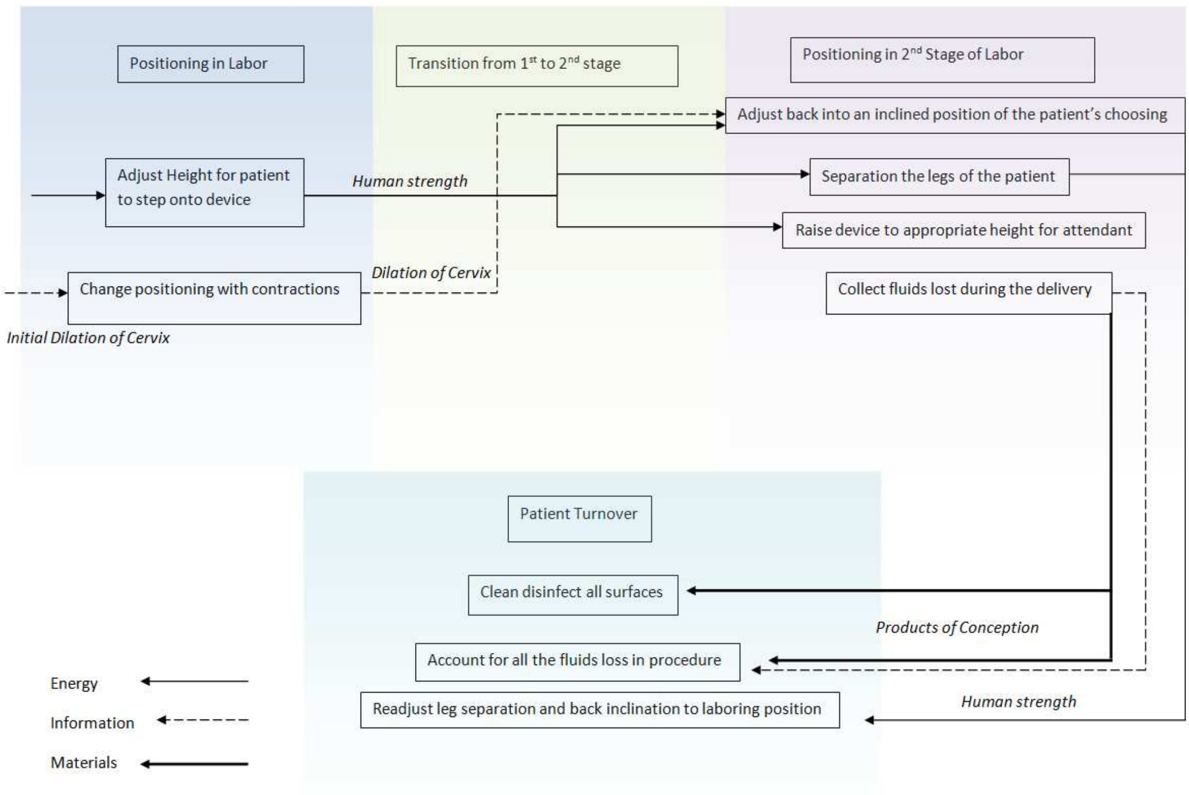


Table 5: List of function based concepts

Optimal Height	Back Inclination	Leg Separation	Access to Pelvis	Fluid Collection	Quick to Clean
Pump	Click click click	stirrups	remove bottom 1/3	funnel	minimal surface area
springs	Pegs present	bars II to feet	fold down	bucket/plastic sheets	few crevices and cracks
Criss-cross	lever system	full foot support	slide under	semicircle	disposable sheets
Crank	Big wheels	rods for knee or calf/feet	lower 1/3 vertically	sliding conatiner	durable surfaces
Pulley System	Pulley System	birthing lane	parting the legs	metal frame for bucket	pleather
Manual telescoping tubes	Criss cross	candy cane stirrups	belt system	piping	rubber covering
Rollers	crank	flexible straps on bar	rocker		joint covers
Inflating	Inflating	u-rod with hooks outside	Inflating		
Rocking	top 1/3 bottom 1/3 connector	contoured u-rod with padding	top 1/3 bottom 1/3 connector		
Fixed height	corner pyramid	square-round with straps	pulley		
	back pillow	grooves in mattress	crank		
	rocking				
	spikes				

Reparability	IV Stand	Pelvic Inclination	Leverage	Transportable
Manufactured in country	Rod	crank	None	wheels
minimal components	hanger	pegs	above the head bar	none
no electrical components	t-rod	lever	cloth to pull on	light weight
		stationary	candy canes	rollers
		rocking chair	vertical rods	tracklighting
		cushion ramp	u-bar	sliding
		lawnchair idea	holes in sides	zipline
		cantelever motion	rubber strap	

The first major function our device must provide is a comfortable labor position. Our device needs to be positioned at the correct height for the patient so that they may safely and comfortably get on and off the bed. When on the bed the patient will likely move around to alleviate pain sensations. Once the patient is dilated 10cm, our device will transition into a delivery position. In the delivery position, the attendant will raise the height of the device for proper access to the pelvis as well as change the back support and leg separation. Fluids are also discharged during the delivery stage and should be collected for recording the amount of blood lost. After the patient is through the delivery stage, the device needs to be cleaned and readjusted for the next patient to use it.

Through the functional decomposition, we generated concepts and mechanisms that would specifically address each sub-function of the device (Table 5). The main categories considered were optimal height, back inclination, leg separation, access to pelvis, fluid collection, reparability, IV stand, pelvic inclination, leverage, and transportability. Some pictures were drawn during this session to further demonstrate some of the details in the table (Appendix E).

CLASS BRAINSTORMING

After we generated our concepts and began the down selection process we were able to have a short brainstorming session with our discussion section. In order to make this session as efficient as possible, before the brainstorming session we presented some of the ideas we had already generated, so that there would be minimal overlap of ideas. We also had the class focus on the areas where our team thought we needed extra support or where we needed more ideas such as in the adjustable height mechanism, leg separation device, and adjustable back and pelvis areas.

In addition to asking students to focus on specific function areas of the bed, we also asked some students to focus on whole concept designs as well so that broader ideas not specific to one particular bed feature were not neglected. Because our team had not returned to generating full system level concepts since our initial individual brainstorming session we were interested in obtaining more of these full concepts from a fresh perspective. We were also interested in gathering more ideas for the features that ranked highest on our user requirement list. These concepts included back inclination, height adjustment, and leg separation. Group brainstorming lists available in Appendix F)

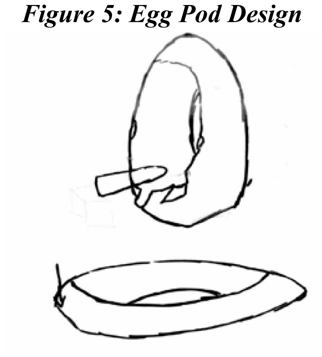
DETAILED DESCRIPTIONS OF FIVE CONCEPTS

The following section gives a more detailed description of five different ideas and concepts that were generated during the entire process. All additional figures are found in Appendix D.

1. Egg Pod

This was a non-traditional whole concept device (Figure 5). For labor, the pod would be in a supine position so the patient could lie down, and the opening would face straight up. When adjusting to the delivery position, a counterweight would be shifted allowing the pod to come up, rotating about "bottom," which is where the patient's feet would be. This bottom is rounded to allow the bed to rotate up more easily. This section can also rock back and forth to allow for different back inclinations during delivery. There are also two panels embedded into the pod around the foot area that slide out to provide foot support and leg separation. A semi-circular piece between the two panels can fall away to allow easy access to the pelvis. Because this and a few of the subsequent concepts are very non-traditional, the entire mechanism is theoretical. As an initial concept, the specified mechanisms for adjusting these devices were not completely thought through.

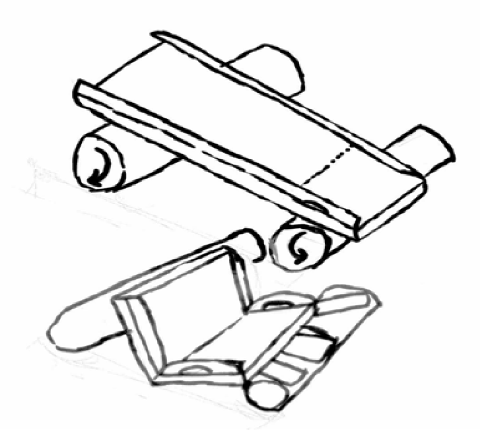
Figure 5: Egg Pod Design



2. Roller

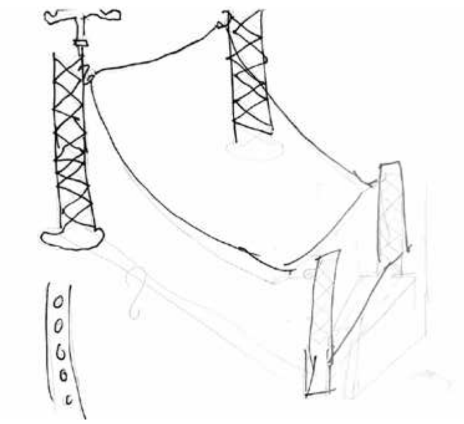
This concept has a flat platform inside that lays on top of two large cylinders for the labor position (Figure 6). There are curved arches on the ends of the platform parallel to the patient for safety so that the patient does not fall out. To transition to the delivery position both cylinders rotate in opposite directions towards the outside ends of the platform which folds the platform in half, and inclines the back and pelvis. There is the potential for the patient to rotate the cylinder under the back so she can adjust her own back inclination. When the cylinder under the pelvis and foot section rolls to the end of the platform, three channels from under the platform can be pulled out and exposed. The outer two channels are for leg support while the middle one is used to facilitate fluid collection and pelvic access.

Figure 6: Roller Design



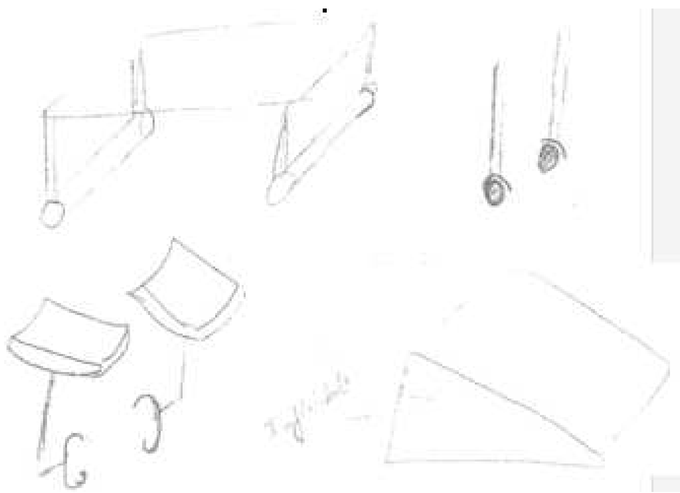
3. Hammock
This is another non-traditional whole concept device (Figure 7). It is based off of a hammock with metal pillars for support. These pillars are sturdy bars with holes at adjustable heights to which the hammock could be fastened. The holes allow the hammock to hook on at different heights which can adjust the height of the entire hammock, or the height of just the back, or even just the pelvis. To access the pelvis, there is a zipper between the legs that opens the hammock so the birth attendant could achieve appropriate access to the patient and the birth canal. Also the pillars at the foot end of the bed could have a bench between them for the birth attendant which would provide a counter weight to balance the front hammock support. The un-zippered part of the hammock could also be used as a kind of stirrup to provide leg separation. Another addition to the hammock is connecting the front of the hammock to the ceiling and creating a pulley system to allow the patient to reach over and adjust her own back inclination.

Figure 7: Hammock Design



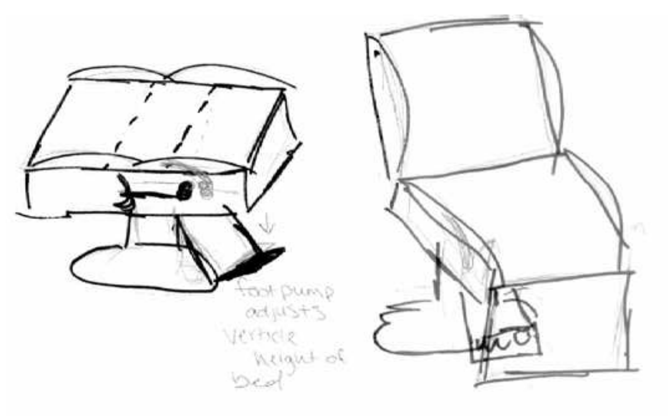
4. Removable Accessories
This concept was based off the idea of not creating an entirely new device. Instead of requiring KATH or any potential buyers to discard their old labor or delivery beds, we envisioned designing accessories that would add-ons to current supine beds (Figure 8). They include a new frame for the bottom of the bed with rollers to make the bed transportable. There are also stirrups that could clamp on the side of the bed, an inflatable wedge to be used for back inclination, and an adjustable bottom mattress that could turn into foot rests and allow access to the pelvis. There is no quick height adjustment feature.

Figure 8: Removable Accessories



5. Recliner
The final concept we are describing is the recliner (Figure 9). This recliner behaves as a standard bed during labor and a supine delivery. This concept has a central support pillar with a foot pump within to provide height adjustment. There is also a crank on the side of the bed for the patient or birth attendant to reach over and pull for back inclination. When the back is inclined, the bottom one-third of the recliner drops down to lay perpendicular to the floor allowing access to the pelvis. This concept can have handles for leverage and railings for safety to prevent the patient and baby from falling out.

Figure 9 Recliner



V. CONCEPT SELECTION PROCESS

Similar to concept generation, concept selection was a multi-step process that included multiple methods. The primary method used included listing all the different concepts by their function, then down selecting by direct comparison within each function. When directly comparing different mechanisms which perform the same function we considered variables such as feasibility, manufacturability, ease of use, ease of repair, surface area and quickness to clean. With these parameters in mind we made our initial down selection.

Before we could begin the concept selection process, we combined all the concepts we had generated thus far. This included all "full" concepts (Figures 5-9 plus Appendix D), and functional mechanisms (Table 5).When compiling all brainstorming we found that it was not possible to compare full concepts with individual components as we found that many of the full concepts i.e. the egg pod inhibited many of the functional mechanisms. Therefore, we had to compare functional mechanisms and the whole concepts served mainly to assist in generating some of those functional mechanisms. Whole concepts were compared first in order to expel overall features our device should possess.

COMPARING WHOLE CONCEPTS

To compare whole concepts we used a Pugh chart (Appendix G). The purpose of the Pugh chart was to compare concepts to a standard or datum device. Concepts were compared against the datum for each design criteria. Each design criteria carried a certain weight, which was based on a three point scale. The most important criteria were given three points, while the least important requirements were given a weight of one. Then the comparison was done using a scale of ++/+/-/- - where each plus was worth one point and each minus was worth negative one point. Summing the product of the comparison score by the criteria weight for each of the design criteria gave us a total score for each concept. This number was used to directly compare the concepts. Whichever concept received the highest score was the "best" concept, while the lowest scoring concept was the "worst." We understand that there is no best or worst design, but for the purpose of comparison we are using these words to name our results.

For our datum or reference concept we used the current labor and delivery beds in use at KATH.. We used a weighting system to account for the variant importance of different features. The most important user requirements (safety, low cost, easy and quick to adjust, and patient comfort) were awarded three points. Less important, but still very necessary user requirements (back adjustment, height adjustment, and access to pelvis) were awarded two points. Finally, easy to repair and fluid collection system were worth 1 point a piece. Additional user requirements were not included in the Pugh chart as we decided they did not find them relevant for this comparison. For example, an IV stand could be easily implemented to most designs; therefore it is not a necessary criterion that influences which concept is best.

Based off this Pugh chart, the "best" designs were the hammock and attachable accessories concepts while the "worst" were the rocker and egg orb designs. However, we believe that these numbers may not be entirely reflective of external factors which would influence the acceptability of certain designs. Because many of the concepts we compared were theoretical and non-traditional, there were many unknowns, which we marked in the Pugh chart with question marks. For example, as the egg orb concept is entirely theoretical at this point, we did not have much basis for assess how much it might cost. We just assumed it would cost more than the current labor or delivery beds, as this concept is novel and details of the mechanism for swinging back and forth would likely be elegant and costly.

Since we recognize that the Pugh chart had some short-comings when dealing with new ideas, causing questionable results, we did not feel comfortable using the results from this Pugh chart to choose our final designs. Therefore we decided to compare concepts addressing only one or two features while incorporating the features from our full concepts. For example, we took the rocker mechanism from the rocker design and listed it with our back inclination concepts.

DOWN SELECTING COMPONENT CONCEPTS

To begin this process we returned to Table 4. As the user requirements “quick to clean” and “reparability” did not contain definitive mechanisms, we allowed these requirements to guide our decision making process. Additionally we had to keep in mind feasibility given the amount of time available for manufacturing and availability of funds.

During the first stage of down selection we selected our top three choices for each of the remaining nine categories listed in Table 5. After the top three choices were selected, we revisited our selections a different day. This allowed teammates to enter the session with a fresh perspective. We re-evaluated the final three choices by comparing the advantages and disadvantages of each design and discussed other significant factors such as reparability, quickness to clean, feasibility, longevity, manufacturability, and ease of use. Below we describe how mechanisms for nine of our user requirements were selected:

1. Optimal Height

In the “optimal height” category, we developed a total of 10 mechanisms to perform this function. Immediately we eliminated concepts which were extremely labor intensive as our 3 week manufacturing timeframe is already quite ambitions! Therefore rollers, rocker, and springs were eliminated. Additionally the rocker concept (Figure 5 Egg Pod) was eliminated as we believed it looked unstable and patients may not feel comfortable laboring and delivering on a device such as this. Inflating height was eliminated as the lifetime was not predicted to be long and it would have to be replaced every time it broke down. The pulley system was eliminated as this concept increased complexity of the design and would require a ceiling. Manual telescoping tubes were also disregarded because they would require a large amount of force inputted by an attendant, thus violating our user requirement of “quick and easy to adjust”. To reach our final three mechanisms the criss-cross director’s chair-like mechanism was eliminated as we could not determine how to keep the bars stationary at different heights. Further we believed this mechanism was in violation of our user requirement “quick and easy to clean” as the force necessary to adjust is likely significant. Our final three mechanisms were thus pump, crank, and fixed height. We believed these mechanisms were feasible as we could machine them in our restricted time frame, they were not complex, and each could be performed by no more than one health care attendant.

Of the final three designs we again assessed the advantages and disadvantages of each. An advantage of the crank is that it is mechanical. This is important as if it broke down it is more likely to be repaired that a hydraulic pump. Further, it could be positioned such that is easily accessible to the health care attendant. A disadvantage is the amount of energy it would require the health care attendant to enter. Further, the less energy the health care attendant is required to exert the longer it will take to move the bed. A fixed height was another concept we thought had standing as it would reduce the complexity of our design by eliminating the adjusting mechanism. We ultimately eliminated this option as our end users strongly desired the bed to adjust to their different heights. Because this feature is primarily for the attendant and not the patient we do not see this as the most important feature of our bed, but none the less we would like to incorporate the wishes of our stakeholders into the design if it is feasible.

Our final choice for achieving optimal height was a pump. The major advantage of this concept is that it would require minimal training as the device requires one motion which is relatively simple and intuitive to perform. A foot pump would allow for easy access since most likely it would be at a central support which is within the attendant’s reach. Depending on the type of pump there could potentially be a wider range of adjustability. A disadvantage of this concept is that the hydraulic pump would be difficult to fix, especially in rural settings. Thus this device would be most appropriate in a limited resource clinical setting as opposed to a rural setting. Another disadvantage we would have to consider with this device is whether or not it would be in the way of the fluid collection system. Because the pump is at the end of the bed, it would need to be on the side to not interfere with the bucket in place for collecting fluids.

2. Back Inclination

In the "back inclination" category we had 13 different concepts, some of which overlapped with the height adjustment mechanisms. For the same reasons described in optimal height, we eliminated criss-cross, inflatable, rocking, and pulley system. Further, the use of spikes to scare a woman to incline her back, and a folding pyramid were unrealistic ideas. Big wheels, as found in the roller concept (Figure 6) were also found to be unfeasible as they would take up excess space in the already congested labor wards. Additionally, it would be difficult to implement such a novel and unrecognizable device into a society which is resistant to change. The back pillow was a favorable concept due to its simplistic design and agency it affords to patients by allowing them to participate in the delivery process. Still, it presented challenges as we are not keen on having accessories as we noticed these frequently go unused. The back pillow was also eliminated due to cleaning issues and strength. Because the pillow would be soft, we questioned the lifetime of the device given a women would be pushing back on it for several hours. Further, the single option of back inclination afforded by the pillow was a drawback as we would like women to have multiple back inclination options.

The final three choices were crank, pegs present, and a click, click, click mechanism similar to that found in many lawn chairs. A crank mechanism was eliminated for the same reason described in the "optimal height" section. Additionally, upon initial consideration the crank design to adjust the back appeared very complicated and we did not think we would be able to spend the requisite time necessary to fully develop this mechanism while also addressing eight other features. An advantage we identified to the click, click, click mechanism was it met our user requirement "quick and easy to use." However we were unsure that this mechanism would be able to sustain the large force generated by a pregnant woman pushing. Therefore we eliminated it as it did not appear sturdy or safe enough to be used in the clinical setting.

Our final choice for back inclination was thus the pegs concept. We identified two distinct advantages to this concept. One advantage was the simplicity of the design. As there is limited time for manufacturing this semester and we have multiple features to machine, it is important for us to select basic mechanisms which are feasible to design. Another reason simplicity is important is that a part is more likely to get fixed if it is simple to repair. The second advantage to this mechanisms is the multiple options for heights. The number of pegs will determine the number of angles the back can be inclined. Since pegs are not difficult to design for, it would be simple to add a few more inclinations once the mechanism is built. A disadvantage we identified with the design is that the attendant will likely have to back of the bed to raise the incline. Based on our observations at KATH, the attendants preferred to remain at the foot of the bed, suggesting a design in the back of the bed may not be utilized. Another disadvantage is that in order to lift the back portion it would require the patient to lean forward, which would potentially be uncomfortable.

3. Access to Pelvis

When down selecting from our 11 "access to pelvis" concepts we eliminated all overlapping concepts already negated in previously discussed sections. These included the rocker, inflatable, and pulley mechanisms. For feasibility reasons the belt system was eliminated. Completely removing the bottom one-third of the device was eliminated because we did not want many different parts since we felt with limited human and space resources, there would not be room to store the bottom third, or for staff to retrieve or remove and store that part. The final concept we eliminated during the initial down selection was parting the legs, which is where the woman would slide down to the end of the bed and her legs would be separated. We decided that this would be uncomfortable for the woman, and the purpose of our project is to eliminate the woman having to move herself from labor to delivery.

After this preliminary down selection we had four final concepts remaining: fold down the bottom third of the bed, slide the bottom third of the bed under the center portion of the bed, lower the bottom third vertically, and a mechanism to raise the top third and lower the bottom third of the bed through a single motion. We selected folding down the bottom third of the bed as this could be performed in a single motions via removing a latch, it would not requiring multiple steps, and the design was straight forward enough it could be repaired in limited resource settings if it broke.

4. Leg Separation

When brainstorming for leg separation a variety of concepts surfaced ranging from traditional to more culturally specific practices. In total 11 concepts were discussed within this user requirement including full foot pushers that are stationary, a birthing lane, a contoured rod with padded semi-circles and candy cane shaped stirrups. Additionally we explored an accessory type stirrup system as found from a group of students from Rice University.[lxxvi] However this device was intended for transportable purposes and was thus flimsy and did not provide support for extended use. This particular feature of our design has evolved from the alpha design as we did not believe the leg separation device in the alpha provided enough lateral range. Further, it inhibited access to the pelvis. After several trips to the Ob/Gyn department at the University of Michigan and discussing with nurses trends in leg separation devices all of them indicated that foot pedals were favorable over stirrups as they gave women more control and agency during the birthing process. We have decided to go with circular rods which the woman's feet could grip while pushing because it gives the woman control, and they are not too complex that if they break down they could not be repaired in limited resource settings.

5. Fluid Collection

Narrowing down the fluid collection system was done very quickly. We felt that the funnel, semicircle, sliding container, metal from for bucket, and piping concepts were all unnecessary since the current system of a plastic sheet and bucket seemed to work well in limited resource settings and only added to the complexity of the design.

Currently in limited resource settings plastic sheets are commonly used to project the mattress and frame of the device. This set up also increases the ease with which beds are able to be cleaned as the sheet is removed, bed is wiped down, and a new sheet is placed on. We do not feel like our device needs to specifically create something to help improve a system that already works effectively and efficiently. Also because fluid collection falls below the must-haves vs. luxuries line we feel that it is acceptable to not provide new innovation in this design.

6. Pelvic Inclination

Brainstorming for pelvis inclination was almost a repetition of other mechanism used for more important features. Our team discussed using a crank, pegs, a lever system and a rocking chair as well as just keeping stationary without any additional mechanisms. However, upon discuss pelvis inclination with expert witnesses (Ob/Gyn's in the U.S.) we came to the realization that an inclined pelvic is not necessary for a labor and delivery device.[lxxvii] Therefore we will have a stationary pelvic position.

7. Leverage

Leverage consisted of a wide range of concepts. Of the eight, the top concepts were candy cane-like shaped handles that would possibly be combined with leg separation, a u-shaped bar that went across the patient's abdomen so that a variety of hand positions would be available, and having simple cut-out holes in the side of the device for the patient to use. After making our list the candy-cane-like shaped handles were decided upon for having the most versatility without limiting the patient's positioning or the attendants' access to the pelvic area.

8. IV Stand
An IV stand is a standard piece of equipment within a major medical facility so not much brainstorming took place in rethinking its design. The standard rod was chosen and the positioning of the rod would be at the head of the bed by the patient's arm or hand where the IV would be inserted. The height of a rod should be adjustable so a telescoping rod is the specific concept chosen.

9. Transportable
Transportable ranked as the least important user requirements, but several mechanisms were purposed which would satisfy this user requirement. The top concepts were wheels under in the supports, no intention of transporting, light weight for lifting easily among several people, rollers and sliding. From our observations and our pro/con lists we decided upon a combination of light weight and no real mechanism for transportation specifically.
When starting concept selection we used the standard method of a Pugh chart and discovered that together concepts and creating pro/con lists helped us to better evaluate the wide diverse concepts.

VI. THE "ALPHA" DESIGN

From our down selected concepts we constructed a preliminary alpha design. This alpha design represented our user requirements and engineering specifications as of Oct. 15, 2010. However our user requirements and engineering specifications have further developed between since Design Review 2. The pictures below illustrate our chosen alpha design concept. This design was put together by assembling the number one mechanism selected under each functional decomposition category. These categories include: height adjustability, back inclination, leg separation and access to pelvis and others. After breaking down our needs into flow of energy, information and material we determined that our bed needed to configure for two different purposes- laboring and delivering. For the labor position the bed must allow the patient to lie down comfortably in a supine position. Our design enables this by remaining flat and horizontal during labor, with a sufficient width of 34" (requirement was >30": Benchmark Bed Currently Used at KATH) (Figure 11). When the woman progresses from the first to the second stage of labor, the nursing staff can change the configuration of the bed in three quick and easy steps. First, she would press the lower one third of the bed in the area in between the legs such that it is parallel to gravity. As the lower one third of the bed is folded down this would give sufficient access to the staff to the patient's pelvis. The mechanism of this would entail a hinge about which the flap could partially rotate. Next the staff can incline the back of the bed by simply lifting up the upper one third of the bed. There will be 3-5 slots on the frame of the bed for a rod to lock the desired inclination. As can be seen, the inclination could be changed based on the patient's preferences and the nursing staff's needs.

Figure 10: Delivery Position

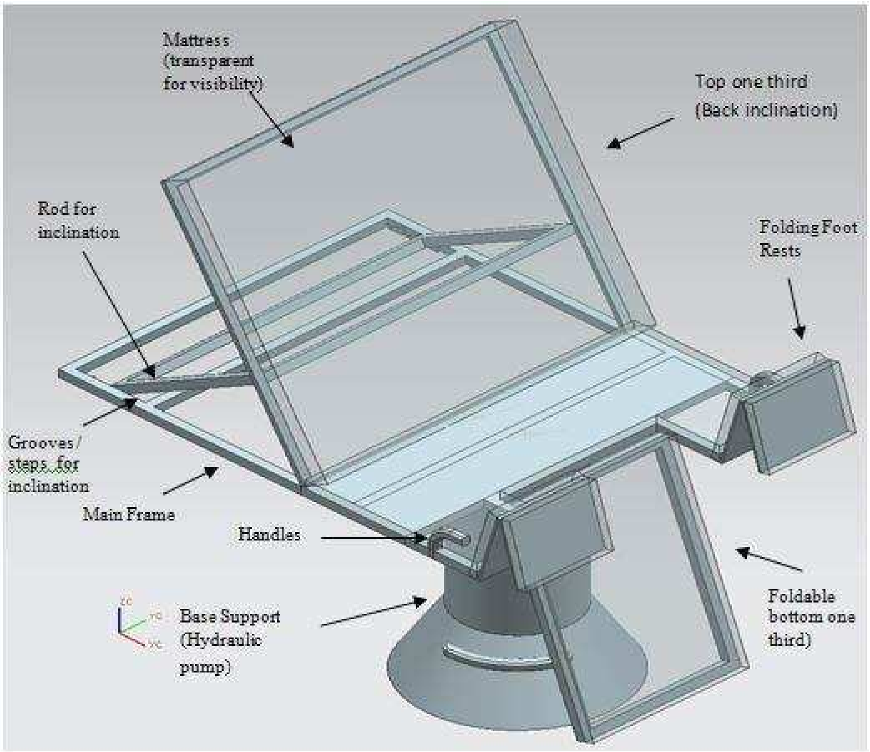
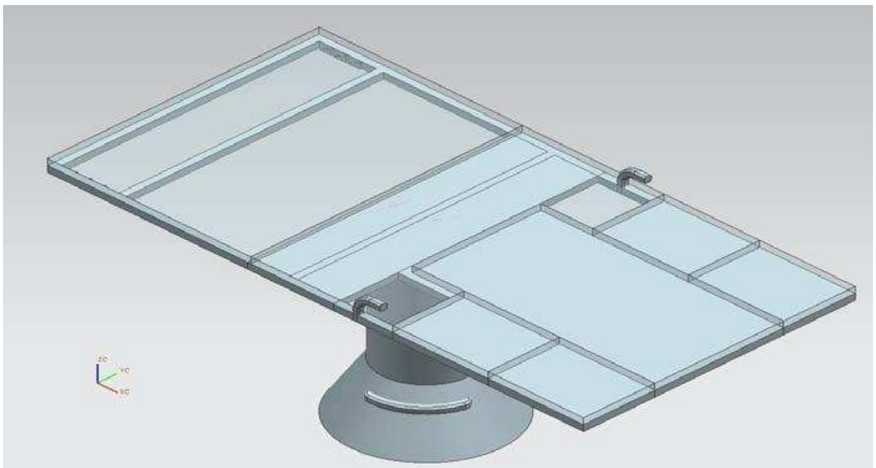


Figure 11: Labor Position



The outer portion of the lower third of the bed will be folded twice to form something like a foot pad (see above in Fig 10). These would stay in place by locking into grooves. We liked this idea, since this removes the necessity of having extra parts to the bed like stirrups or straps. We are essentially using a part of the mattress (which is translucent in the above drawings) to serve as leg separation, also providing padding to the foot. This mechanism further increase access to the patient's pelvis as this section of the bed folds back out of the way. At this the bed is fully reconfigured and the woman can give birth in this position. In our design we have also provided two handles by the patient's side for her to hold while pushing. This will give her extra leverage to pull since we noticed that women at KATH were always trying to hold on something when they push during the second stage of labor.

Another important feature in this design was the height adjustability to attain the optimal height for the nursing staff. This could be done if needed by a foot pump on the right side of the bed which works on a hydraulic pump mechanism. It is to be noted that we did not include any extra container or system for fluid collection during childbirth. Based on our interviews in KATH and observing videos of deliveries in cultures like Haiti, we determined that the hospitals could still use their fluid collection containers on our device thereby reducing complexity and cost of manufacturing for us. However, we do not want to get tied down to this solution yet and are open to ideas that incorporate a fluid collection system without increasing the cost of complexity.

Once the baby is delivered the bed can be made flat again following the same procedures in a reverse manner. The whole design reemphasizes our goal of having a streamlined birthing process where the patient doesn't have to shift between beds either before or after the delivery.
This is illustrated in a prototype we constructed (Figure 12-15). Figure 12 illustrates the back of the device inclined, and feet pads in the upright position. Figure 13 illustrates the bed in the laboring or reclined position.

Figure 12: 3D Model

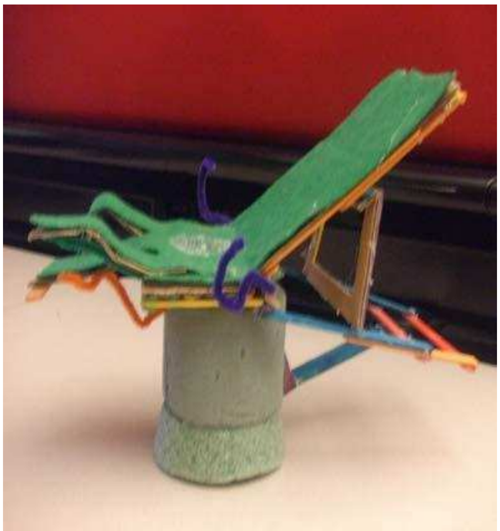
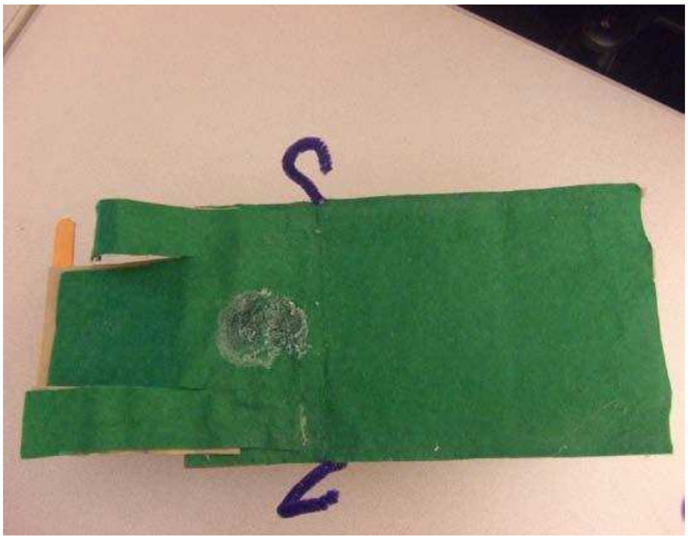


Figure 13: Top View of 3D Model



KEY LEARNINGS FROM ALPHA DESIGN

Now we would like to draw attention to the process of making our design mock-up and the important key learning we got out of it. We made the entire design out of Popsicle sticks, Styrofoam, wires, cardboard and velvet paper. We made the basic horizontal frame out of sticks using it as long structural members and using cardboard as metallic sheets (Figure 12,14,15). We rested the horizontal part on the bottom support made out of Styrofoam (Figure 12). Here we faced our first challenge. We had conceptualized supporting the horizontal frame at about the middle part of the frame. While building it we realized that we need to have a longer back/head rest area as compared to the foot rest area and this misbalanced the frame about the base support. To stabilize the structure we had to put another stick coming out of the base support that held the upper one third of the frame from underneath it. Also, initially we had envisioned a mechanism through the central support which connected the bottom third of the bed with the top third of the bed such that both portions of the bed could be adjusted in one movement. We were unable to construct this mechanism since that would require a stick to go right through the center of the base support connecting the top and bottom one thirds of the bed. This was not possible since we had already added a support (as the one mentioned above) at that same location for the frame. We are now looking into connecting the two ends by a mechanism that goes around the base support.

Next when we were making the foldable foot rests, we realized that it would be really difficult to fold the mattress (in the leg region) and if hinges were added then they would act as locations for fluids to seep in and clog. We now have to come about with ideas to easily fold that section of the bed and minimize the amount of crevices at the same time. We will accomplish this through selecting a medical foam mattress pad which we can cut into pieces to carefully fit the folding portions of the bed such that flexibility is enabled.

Figure 14: Back View of 3D Model

Figure 15: Delivery Position of 3D Model

Finally, the model helped us think about the locking mechanism for back inclination. We thought of having grooves in the frame for hanging rod to lock in. The grooves were designed in a way that they locked the rod only in one direction. Through this we could increase the inclination from one step to another without having to lift the back to take out the rod from the previous step. This could be thought of as the zip tie mechanism where the tie slips in only one direction.

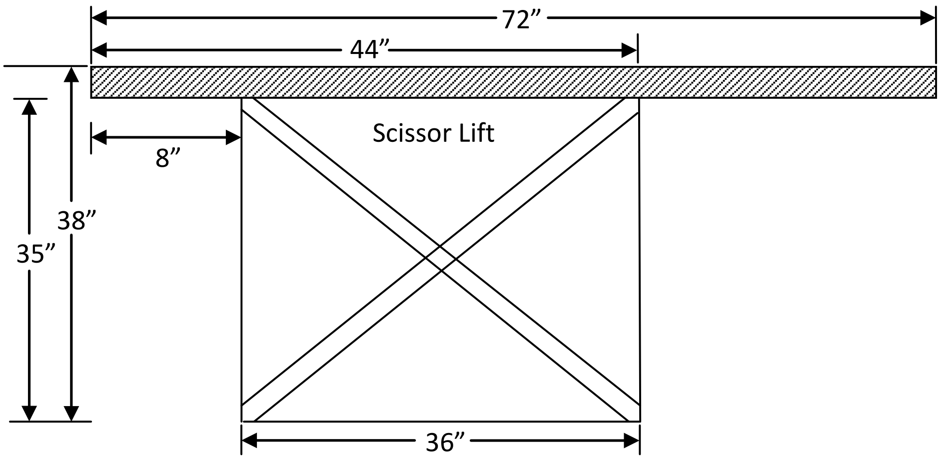
VII. PARAMETER ANALYSIS

To check the validity of the gamma design, our final ideal design, we had to make detailed decisions on specific parameters. Detailed drawings of key components and features can be found in the following Final Design Description section. Rigorous engineering analysis was done on necessary components that were both design drivers and key features. All values for material properties were obtained from Hibbler's *Statics and Mechanics of Materials*[lxxviii] and the ASM International Materials Handbook[lxxix]. Previously written alpha engineering analysis assisted in the performance the following section (Appendix H). Drawings below are not to scale.

BED FRAME

The bed frame is split into two separate pieces, but has a total length of 72in. The first piece, the front frame, supports the back and pelvic regions and the second supports the bottom one-third meant for the legs and feet. The scissor lift will have a length of 3ft and a width of 2ft. Descriptions of why these dimensions were chosen can be found in the Final Design Description section. A diagram of the bed frame and scissor lift is below in Figure 16.

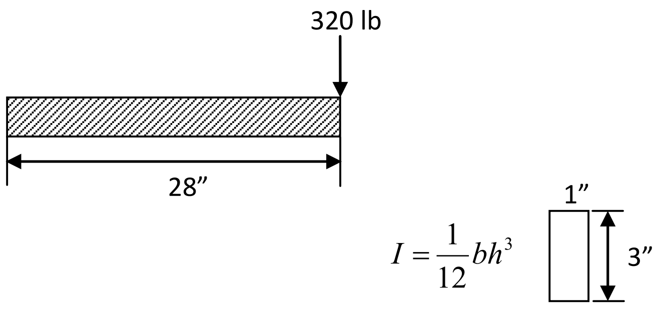
Figure 16: Diagram of Bed Frame with Scissor Lift



The bed frame was modeled as a straight beam using a load of 640lb (reasoning for this value given in Engineering Specifications section) for the safety factor of 2 to check for bending on each end. Since there are two sides to the frame, we divided 640 by the two, leaving us with a total max load of 320lb.

This analysis was done at the end of the foot section (bottom-third) of the frame since that would create the maximum moment. This takes into account a situation in which someone were to sit at the end of the bed. This analysis is strictly to confirm that the frame itself will not deform under the weight of 640lb. The free body diagram (FBD) of this analysis can be found in Figure 17. Assumptions were made that the bottom-third piece of the bed frame was firmly fixed at one end. Two hinges actually connect the two parts of the bed frame with two latches on the sides to support the bottom-third and keep it up against the rest of the frame. The analysis to support this design choice can be found later in this section.

Figure 17: Force at Maximum Moment



$$I = \frac{1}{12} bh^3$$

$$\sum F = 320lb$$

$$M = F \cdot d = 320lb \cdot 28in = 8960lb \cdot in$$

$$\sigma_{\max} = \frac{Mc}{I} = \frac{(8960lb \cdot in)(1.5in)}{\frac{1}{12}(1in)(3in)^3} = 5973.33psi = 5.973ksi$$

$$\sigma_{\max} = 6.0ksi$$

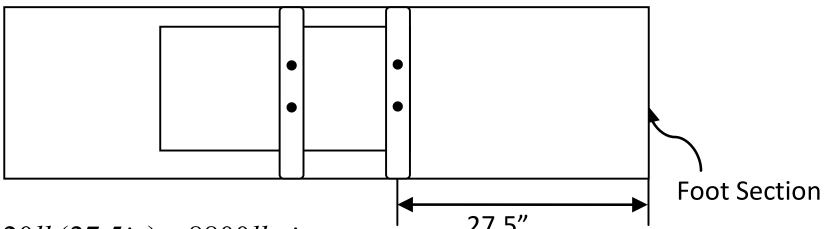
$$\sigma_Y = 21ksi$$

$$\sigma_{\max} < \sigma_Y$$

Where *M* is the moment, *c* is the distance from the centroid to the edge where force is applied, *I* is the second moment of inertia, and σ is the stress. Since the yield stress of aluminum (σ_Y =37ksi) is higher than the max stress, with a safety factor of two, bed frame will not bend.

The next analysis required is to make sure the bolts, shown by the black dots below in Figure 18, connecting the bed frame to the central scissor lift will not fail. To get the maximum forces on a bolt, we take the moment from max load of 320lb at the foot end of the bed to the first set bolts. Since there are two bolts, each will take half of the total moment. Each bolt is has a diameter of 0.25in.

Figure 18: Top View of Bed Frame Bolted to Scissor Lift



$$M = 320lb(27.5in) = 8800lb \cdot in$$

$$\sigma = \frac{8800(1.5)}{\frac{1}{12}(1)(3)^3} = 5.867ksi$$

$$\sigma_{bolt} = \frac{5.867ksi}{2bolts} = 2.933ksi$$

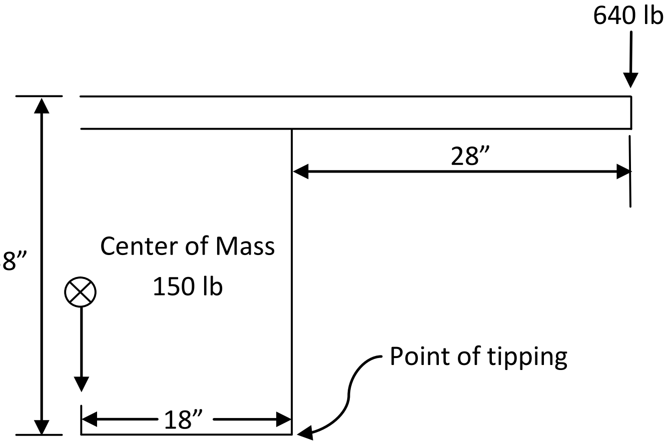
$$\sigma_Y = 36ksi$$

$$s_f = 36/3.933 = 12.27$$

The stress due to the moment force on the bolt is below the yield stress of steel (σ_Y = 36 ksi). With a safety factor of 12.27, the bolts should not fail. Yet, we plan to use more bolts in case there is combined loading on the bolts, and in case the weld joint is not completely fixed.

The final analysis that we did on the frame and lift was to validate that the entire bed would not tip over when loads were applied. A free body diagram of this analysis is in Figure 19. Assumptions were made that the center of mass of the scissor lift occurred at the center of the lift, and that the lift was modeled as a solid block. Also assume friction and no sliding. Again, the analysis was done using the bottom-third portion of the frame because that has the longest moment arm. The total weight of the bed frame is 50lb and the scissor lift weight is 100lb.

Figure 19: FBD of Frame and Scissor Lift from Center of Lift



Tipping occurs when:

$M = M$ or $\sum M = 0$

$150lb \cdot 18in \geq 640lb \cdot 28in$ to not tip over

$2700lb \cdot in$ is not greater than or equal to 17920 lb, therefore the bed will tip over.

If we use the actual target weight of 320lb, the bed will still tip over. There are two options to correct for this. The first is that we can make the scissor lift very, very heavy, around 500lb. If the lift weighs 500lb, then it will be able to withstand a 320lb force at the end of the bed without tipping. Another option is to not allow any weights of 320lb at the end of the bed. As 320lb is the weight of a pregnant 95th percentile woman, the chances of this load sitting at the very edge of the bed is unlikely. Also, the most likely weights that will be on the bottom-third is the weight of women’s legs, and this load would occur at the center of the bed support, not at the very end, maximizing the moment force. If the lift table was weighted to 200lb and the force exerted on the bed was at 14in from the edge of bottom-third, the system could withstand a 260lb force without tipping. Therefore, as long as it is indicated that proper use does not include sitting at the edge of the bed this design is safe enough for use.

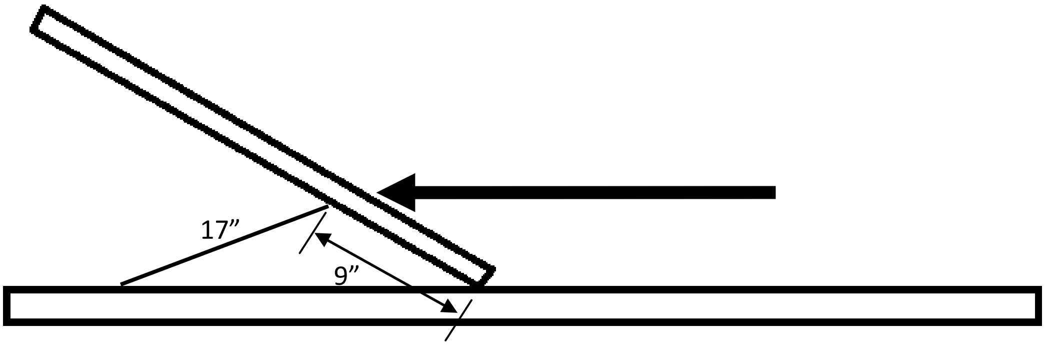
BACK INCLINATION

The next decision that had to be made was deciding at what location to put the back inclination support in relation to the back frame. First of all, we decided that the back inclination should be located at the position where the patient would be pushing the hardest. The reason the back inclination support should be placed there is to cancel the moment at that point, reducing the total moment force that will occur on that support.

We estimated this location to be mid-back, based on the deliveries we saw in Ghana and US in over a month. We observed that women have their back curved and they exert force on the back inclination from approximately their mid-back (*no formal data is available but a safety factor of 2 will account for errors in approximation). We took the position of the mid-back of the 50th percentile women by dividing the whole back length by 2.[lxxx] A 50th percentile woman was used to optimize the support for the average size and not the extremes.

From this calculation we determined the height of mid-back from the buttocks to be 9” (Figure 20).

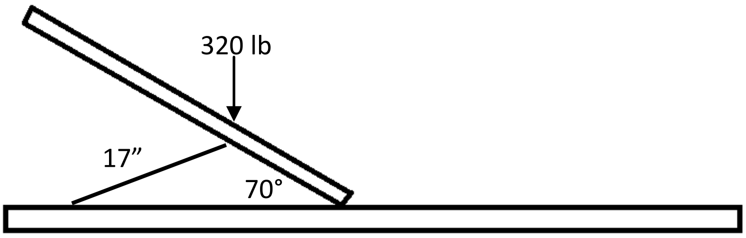
Figure 20: Force Diagram of Pushing Patient



Using the distance 9” we then chose the back if the support bar to have a length of 17” so that when the bed was in the supine position, it would fit under the back frame, but still within the bed frame. Using these values we found that the furthest peg (corresponding to a 70°) should be 8.6”.

We then ran analysis on the back inclination to test the compressive force on the adjustment rod (17” rod). We used our max load of 320 lb for this analysis distributed over the two adjustment rods (Figure 21).

Figure 21: FBD of Compressive Force on Adjustment Rod



$$F = \frac{320lb}{2}\sin(20) = 54.723lb$$

$$\sigma_c = \frac{F}{A} = \frac{54.723}{\pi(0.75/2)^2} = 123.87\,psi$$

$$s_f >> 2$$

With a safety factor much higher than 2, this adjustment rod will be able to support the weight any patient.

LEG SEPARATION ANALYSIS

For the leg separation device we first calculated if the foot rest stoppers would be able to take the load of a woman pressing on the foot rests. These stoppers are shown in Figure 22a and Figure 22b. The 150lb force used in the analysis is based off literature of the maximum force a woman could leg press.[lxxxi] This max force was 300lb, but between the two legs, we assumed each leg could exert 150lb on each foot rest. The free body diagram of this analysis can be found in Figure 23.

Figure 22.1 and Figure 22.2: CAD drawing of foot rests and stoppers

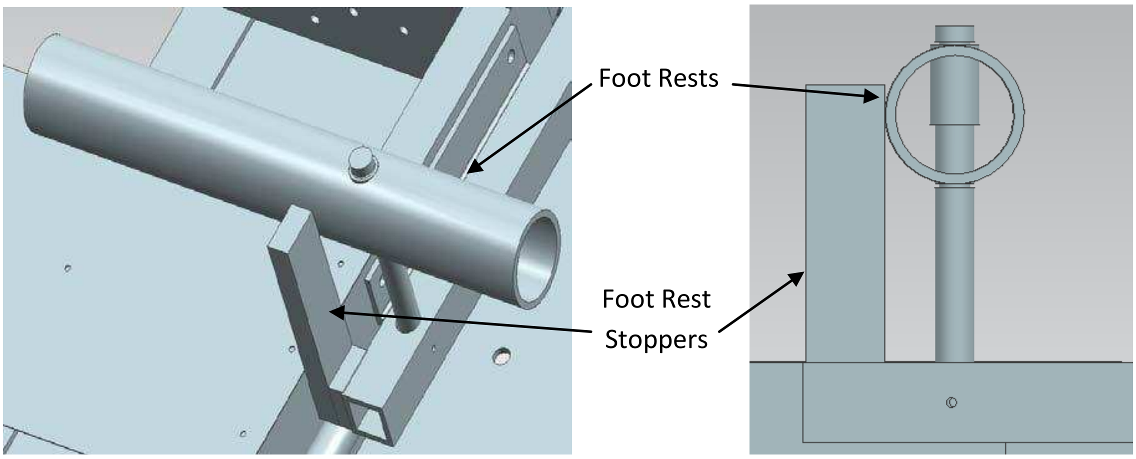
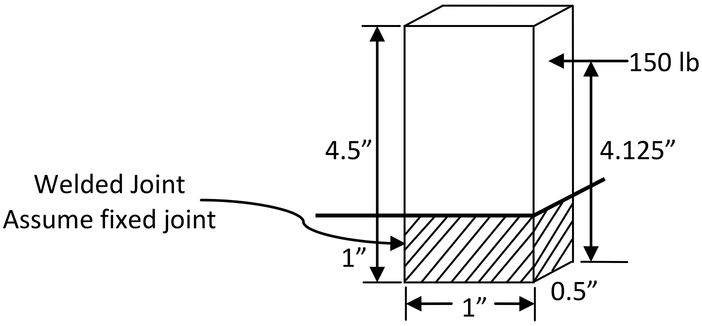


Figure 23: Foot Rest Stopper



$$F = 150lb$$

$$\sigma_{\max} = \frac{(150lb)(3.125in)(0.5in)}{\frac{1}{12}(0.5in)(1in)^3} = 5625psi = 5$$

$$\sigma_Y = 21ksi$$

$$s_f = \frac{21ksi}{5.625ksi} = 3.73$$

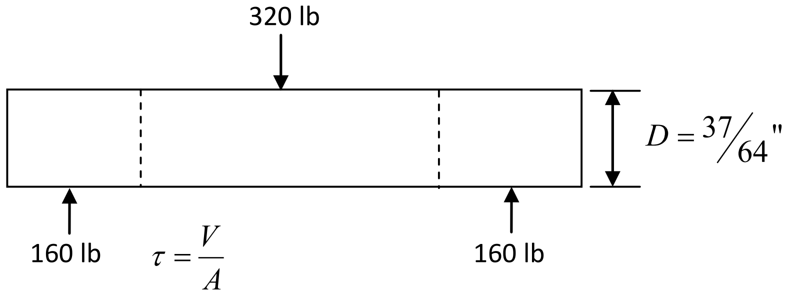
With a safety factor of 3.73 these stoppers should not deflect if a woman exerts a 150lb force.

BOTTOM HINGES

The last key component that we analyzed was the hinge that will be used to hold the foot section of the bed to the bed frame. These hinges will only need to hold the weight of the foot frame and mattress when then foot section has been lowered. We have chosen to use two friction hinges. Part number and specifications can be found in the Bill of Materials. The specifications of these hinges state that they can hold a 450lb load.

The force body diagram of this hinge is shown below in Figure 24. Analysis was done assuming double shear. We are using a 320lb force though the only load these hinges will hold is the weight of the foot frame and mattress. The specifications of these hinges state that they can hold a 450lb load, so we have decided to use two hinges again to remain conservative.

Figure 24: FBD of Bottom Hinges



$$\tau = \frac{V}{A}$$

$$\tau = \frac{320lb}{\pi(0.289)^2} = 1219psi$$

$$\tau_{fail} = 10.152ksi$$

$$s_f = \frac{\tau_{fail}}{\tau} = \frac{10.152}{1.219} = 8.2$$

Based on the above calculations, the hinges we have chosen will support the bed frame without failing. Another specification provided, was that these hinges could withstand only 35 lb ·in torque. Since we anticipate there will be some torque, it reinforces our decision to use two hinges.

SIDE LATCHES

The final key component of our design that requires theoretical analysis is our side latches. These latches hold up the bottom-third of the bed and essentially take all the loads exerted on the bottom-third of the bed frame. Figure 25 below shows the placement of the side latches on the frame. The dimensions and subsequent analysis on the latch rod is shown in Figure 26 and below. As in earlier analyses, we are using a load of 320lb. Since there are two latches on each side, the maximum load is divided by two.

Figure 25: CAD Drawing of Side Latches and Rod Attached to Bed Frame

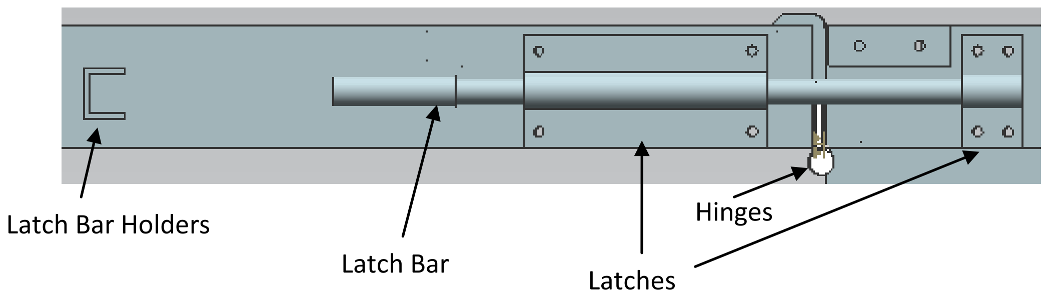
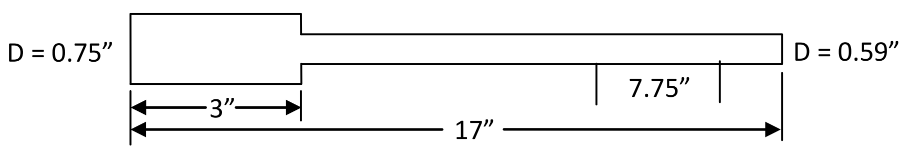


Figure 26: Dimensions of Latch Rod



The moment from a load on the end of the bottom-third causes an internal load that requires a counter moment that must come from these latch bars. $M = (160lb)(28in) = 4480lb \cdot in$. This moment force is distributed in the space between the two parts of the latches. $F = 4480lb \cdot in / 7.75in = 578.06lb$. This force compresses the latch rod, yet this stress is distributed along the entire length of the latch. The larger half of the latch is 6in, while the smaller half is 1.5in.

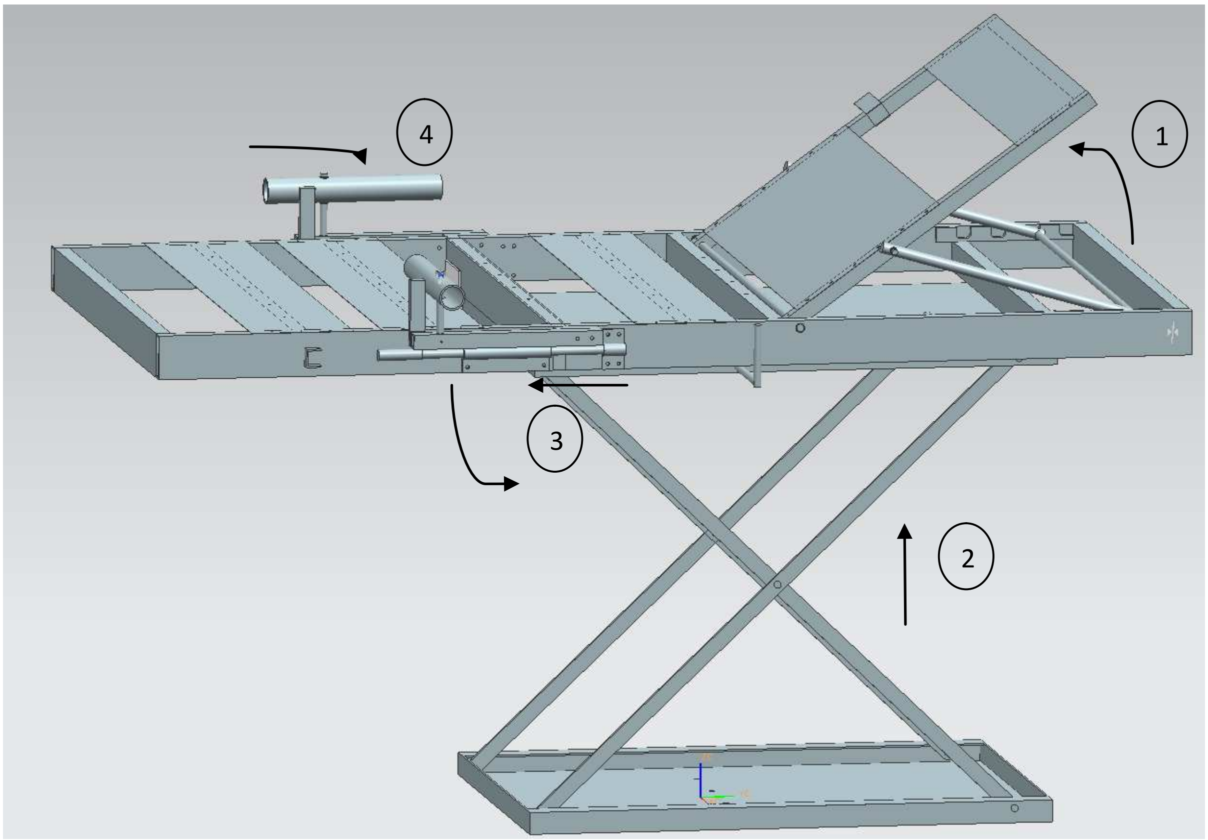
$$\sigma = \frac{P}{A} = \frac{578.06lb}{(0.59)(1.5)} = 653.180 psi$$

This stress is much less than the yield stress of steel (σ_Y=36ksi) and analyzed with this method will not fail.

VIII. FINAL DESIGN DESCRIPTION

The purpose of this section is to discuss and explore our design in detail. We will provide a description of the mechanisms our bed entails and the purpose of each mechanical aspect. A full side profile of our device is illustrated in Figure 26 and an isometric view is provided in Figure 27.

Figure 26. Side-view Illustrating Components of the Bed and Motions



The steps to adjust the bed from the laboring position to the delivery position are as follows :

1. The back inclination is adjusted by grabbing the fabric handle on the side of the bed between the mattress and frame. Then a long rod can be fitted into three different angles based on patient preference.
2. The height is adjusted ideally with a hand crank located at the side of the bed around the pelvis region to raise the bed for the attendant's preference.
3. The lower third is rotated downward through latches on either side of the frame which are released by pulling rods toward the foot of the bed.
4. Then the foot rests have the ability to turn in perpendicular to the patient's feet for leg separation.

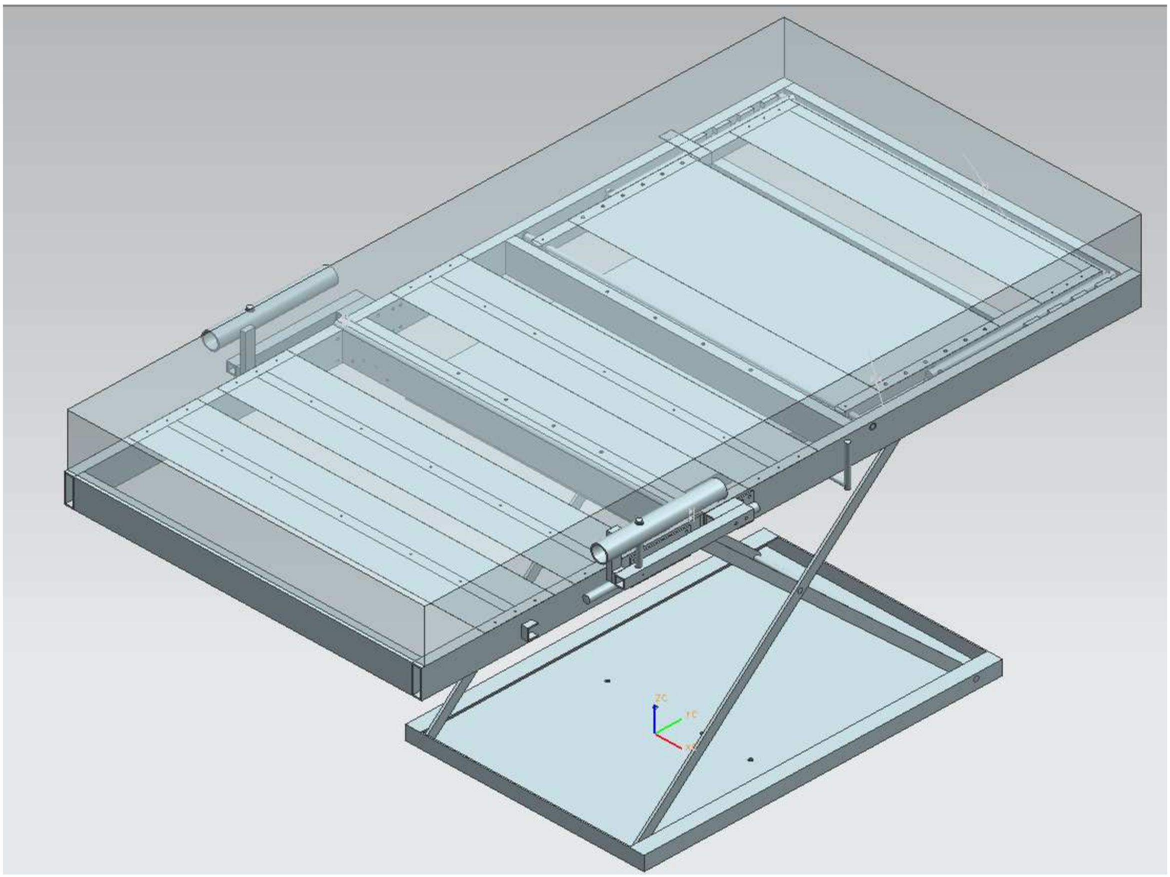
MAIN STRUCTURAL FRAME

Having sufficient length and width on the mattress is important for patient comfort since a laboring woman can spend a considerable amount of time on it (up to 20 hours). Our final dimensions were influenced by anthropometric data as well as information from interviews conducted at KATH. The 95th percentile height for American African women is 68.4"[lxxxii] Because the labor ward was packed with beds on both sides of the ward, it is important to limit the bed length such that sufficient isle space between the two rows is present. The length of the present beds is 72" and the health care providers at KATH thought a similar sized mattress would be suitable. We finally chose a total frame length of 72" giving us a mattress length of 72" (two 1" rods of the frame on both ends of the mattress). The 72" mattress satisfies our requirement, exceeding the requirements for 95th percentile women. The bed should also accommodate women who are taller than 72" as many women do not lay down fully extended and stretched out.[lxxxiii] Therefore the length of the woman's laying position is usually less than her standing height, and if necessary she can bend her legs to fit onto the bed.

The width of the mattress was determined based on our interviews at KATH and their feedback about their present beds. Additionally our interviews with the nurses at the University of Michigan Labor and Delivery Unit provided further support for our design. The staff at KATH felt that their present beds' width of 34" was wide enough, and increasing it any further would restrict space in between the beds. Based on this, we have chosen the frame width to be 36", providing a mattress width of 36" due to the two 1" frame rods on both sides. A width of 36" also supports the dimensions of our benchmarked beds as most of them are around the same width[lxxxiv].

The frame of our design is divided into three main parts: the back inclination, pelvis section and the legs section. We have determined the length of these sections using the ratios of the three sections from our benchmarking data of other labor and delivery devices. The pelvis section will be 15" long, with both the legs section and back inclination equal to 28". Based on the engineering analyses shown in the previous section, the frame will be made out of 3"x1" aluminum tubes with a wall thickness of 1/8". Aluminum was selected as it is lightweight and less expensive than comparable metals such as steel. Also it has sufficient yield strength for our requirements and is anti-corrosive.

Figure 27: Bed in Supine Labor Position



For the frame, aluminum is intended for the final design specifications and was used in the prototype to test of stability of the basic frame. Subjects were asked to get onto the bed prototype and no signs of deflection were seen or detected in the basic frame. Subjects were also asked if they felt safe and if they felt that the bed frame fit them. All women scored the fit of the bed well and the average score for perceived safety was also fairly high. The basic frame was expected to not fail with a safety factor of at least three and match the expectation for the final design. Since the prototype was the same in this aspect, we expect the final design to hit this target.

MATTRESS

We searched a wide variety of mattresses which ranged from $5999[lxxxv] to $40[lxxxvi]. We looked for a cost effective foam mattress that is acid resistant, waterproof and antibacterial. We finally decided to incorporate the *Invacare 5180 Foam Hospital Bed Mattress* since this mattress had all the qualities mentioned above and at $149 it was within our budget (Figure 28).[lxxxvii] This mattress is mid-firm and is designed to aid in prevention of pressure ulcers.

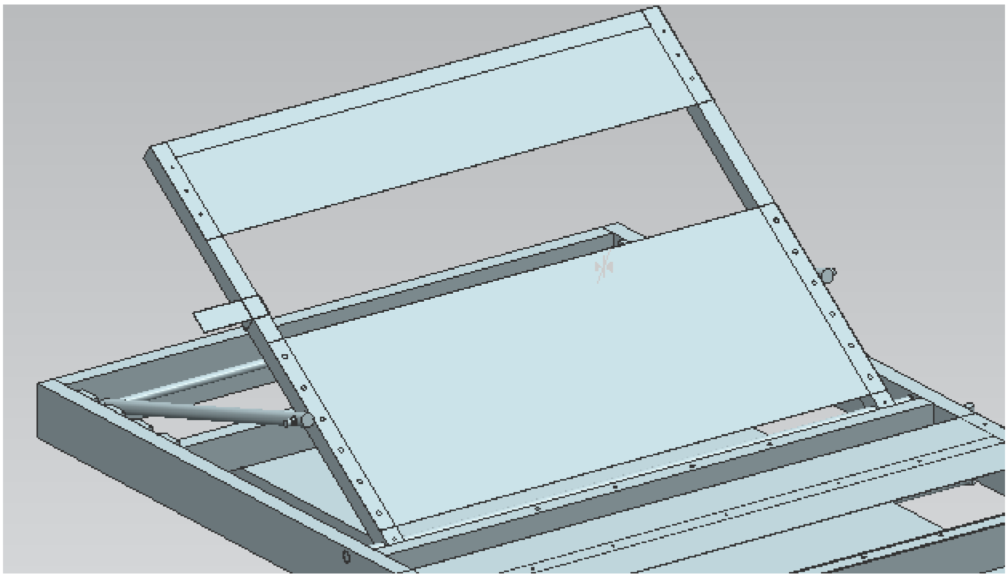
Figure 28: Invacare 5180 mattress we have to purchase.

This mattress is sized at 80"x36" and it would be cut in two pieces based on the dimensions of our back inclination section, and legs section (described in detail below). The mattress will then be covered with a vinyl sheet for each part letting them bend at the various desired angles. The upper mattress was cut slightly where the back and pelvis sections meet underneath to allow for bending when the back is inclined. The mattress used for the prototype was validated as comfortable through subject testing of varying heights and weights. The mattress fit our specified dimensions but not the medical standards needed for patient use.

BACK INCLINATION

The back of the bed inclines to 0°, 35°, 55° 70° from the horizontal. The 70° maximum was our user requirement specification based on our interviews at KATH and our mentors in the U.S. The horizontal position will provide a flat surface during the first stage of labor and the inclination will be mainly used during the second and third stages. A U shaped rod will be used to hold the back at various inclinations. This aluminum rod is made up of two ¾" rods joined together by a 1/2" rod. There are slots on the frame where the U shaped rod will lock into. The change in inclination will be done manually by the attendant and can also be done by the patients themselves.

Figure 29. Back Inclination at an Angle



The U shaped rod is attached to the back inclination frame with the help of the retaining rings shown in the figure 29. A horizontal ½" rod will be milled through the back inclination frame. This horizontal rod will be free to rotate about its lateral axis. While lying flat, the U shaped rod will fit into the gap between the back inclination frame and the main horizontal frame. The back inclination frame is attached to another ½" horizontal rod with a dowel pin and this rod will be slip fitted through the main frame.

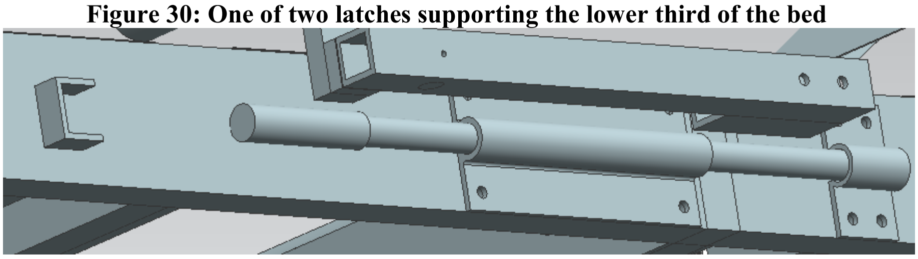
The angles were measured on our prototype and meet these requirements for our final design. The prototype did not have a handle to pull up on the back section which will be ideal for the final design. After receiving comments during subject testing, a handle was suggested for ease of access to the back panel. The force need to lift the back panel fell well within the target. The prototype performed as the final design with exception of the handle. The final design meets the angles needed for ease of delivery and addition of the handle increase ease of use for the attendant.

LEGS SECTION

The legs section frame is 28" x 36" with a 28"x36" mattress. This section is attached to the pelvis section using two hinges. The two hinges will provide attachment, allow the legs section to fold down as well as prevent any twisting in the horizontal plane of the bed. When not folded down, the legs section frame will be fixed to the pelvis section using two latches on the side. To fold it down during delivery the attendant would have to manually unlatch the frame from the two sides. We have recognized that this could be a hurdle in the ease of use. After further discussion the two latch system was preferred for safety purposes. A one motion latch could be a hazard if the single bar is accidently pushed causing the entire lower third to be released. We evaluated that a two latch system worked for several body sizes and fit within our requirement for adjustment time.

Materials used for the lower third and latch system in the prototype fulfilled those specified in the full design. The latch rods were made from steel and the brackets from aluminum. For validation, subject testing showed that the latches were easy to operate and the weight of the lower third manageable for all subjects. The force required to rotate the lower third also falls beneath the maximum target.

Figure 30: One of two latches supporting the lower third of the bed

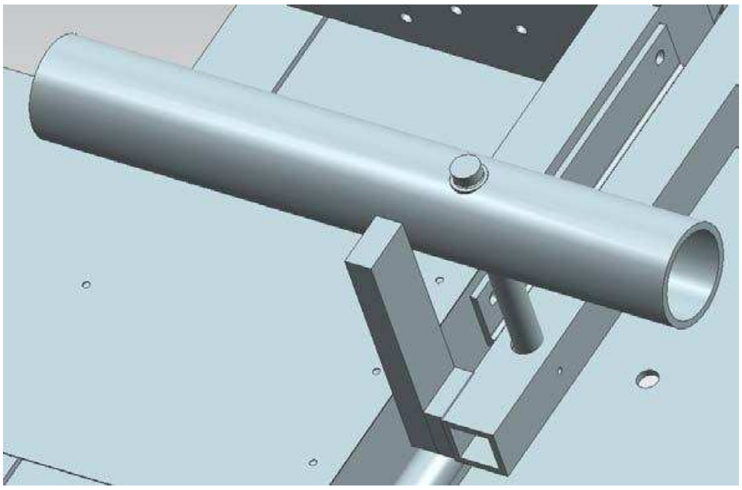


All the validation for the latches and lower third could not performed due to lack of instruments and budget restrictions. Force testing still needs to be conducted on the latches and was not accomplished because the proper sized weights could not be attained. Also the lift used in the prototype prevented the lower third from being able to clear the floor. In our final design the lift used will be no lower than 29" preventing the lower third from hitting the floor. We will have to perform further analysis for now until the correct weights can be used for testing.

FOOT RESTS

The purpose of the foot rests is to separate the patients' legs and provide the physician clear access to the pelvis. It also provides the patient with a component to push against. This part of our design has evolved since DR2 due to considerations about simplicity of fabrication, material use and our meeting with our mentor Dr. Anderson who has worked in low resource settings like Ghana, Haiti and India. The rods emerged over platform since they are easy to orient in the labor position while not compromising on any functionality over the platforms. These rods can be turned and kept parallel to the length of the bed (Figure 31) to avoid protruding out of the bed. For delivery, they can be easily rotated 90 degrees and secured parallel to the width of the bed using a pin joint (Figure 31). A stopper is used to keep the foot rest in place while a woman is pushing on them during delivery but stores away while in the labor position. These are easily moved for the patient after the attendant unlatches the lower third of the bed.

Figure 31: Rods and Pin Joint [lxxxviii]



The rods are 12” long in total to allow for three foot widths of space and provide a wide range of angles for separating the legs. The diameter of the rod is 1-3/4” based on the average foot arc length and will enable a firm foot drip.[lxxxix]

The foot rests for the prototype were made of aluminum and for the final design aluminum would also be used. The operation of the prototype is the same as the final prototype with the exception some dimension changes. The validation for the prototype revealed needed revisions in parts of the design. In the prototype, the force tested that caused yielding was about 30lbs. This value falls far below our target of 150lbs per foot rest. The purpose of a prototype is to conduct validation test and evaluate the results to see if targets are met. In this case the goal was not met so a redesign had to be analyzed to replace it. With new analysis that includes a higher safety factor, the final design foot rests should meet the target set with 150lbs.

SCISSOR LIFT MECHANISM/ BASE SUPPORT

Height adjustability was ranked number five in our user requirement and to address this we are using a scissor lift mechanism. The top and bottom plates of the scissor lift are 36” long by 24” wide. These dimensions have been selected in a way to maximize the material selection for the main frame by reducing the moments in the frame rods. The load of the scissor jack lift is on the attached to the cross bar. The lift has a capacity of 500lb, which is well above our requirement of 320lb. Also it has a height range of 28” to 34” and thus satisfies our user requirements. This table will be attached to the main frame with the help of 8 bolts on 2 of the horizontal rods (Figure 32-33) and will be welded to the metallic frame. These reinforcements make it sturdy enough to not move with respect to the main frame and work like one solid structure. The prototype lift was made of steel and the final design lift is also going to be fabricated from steel. The hydraulic lift has a foot pump for control the height where as the scissor jack will use a mechanical crank that is located on the side near the pelvis of the patient. The prototype lift was on wheels, too short, and too small. It showed functionality and allowed us to test ease of use on subjects operating the bed. To validate the final design, the custom scissor jack will need to be evaluated using a series of weight tests and subject tests.

Figure 32. Scissor table with a Scissor Jack

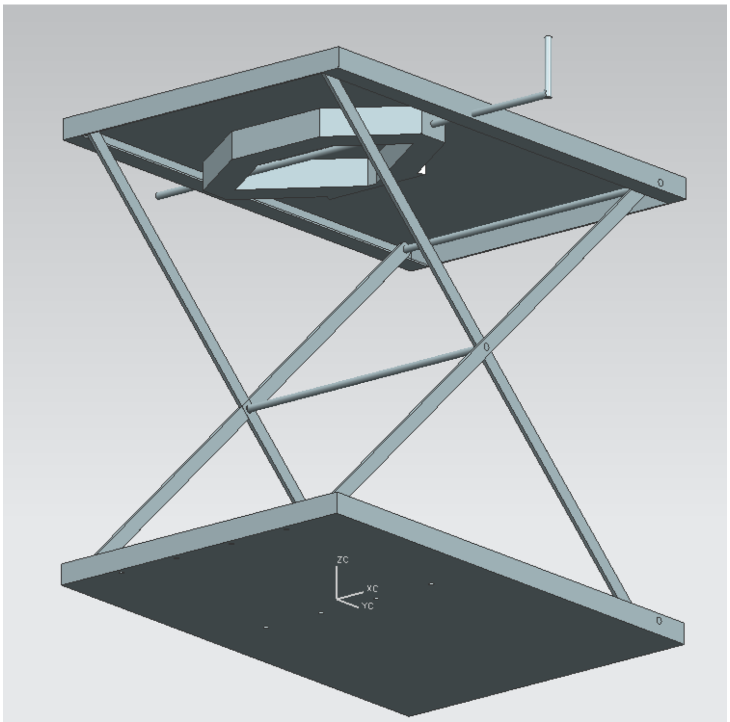


Table 6: Parts List

Stock	Material	Dimensions	Price	Distributor
Solid Rod	Unpolished aluminum	¾" diameter, 36" length	$11.45	McMaster
Solid Rod	Multipurpose Aluminum 6061	D: ¼", L: 36"	$7.57	McMaster
Solid Rod	Aluminum Allow 6061 anodized	D = ½", L: 6'	$13.78	McMaster
Solid Rod	Aluminum (6061)	D= ½", L: 12"	$5.96	McMaster
Sheet metal	Aluminum Alloy 3003	Length 36" w:24", t:0.02"	$15.59	McMaster
Hinges	Base: Acetal plastic, pin: polycarbonate	Pin d: 37/64", screw size ¼"	$8.26 (need 2)	McMaster
Solid Rod	Aluminum (Alloy 6061)	D = 1.75", L=12"	$14.67	McMaster
Solid Rod	Multipurpose	D = 1.5", L=36"	$31.04	McMaster

	Aluminum (Alloy 6061)			
Hospital mattress cover with zipper	Vinyl mattress cover	42" x 80" x 7"	$24.95	Specialty Medical Supply, Manufacturer: Invacare
Square Tube	Alloy 6063 Ultra-Corrosion-Resistant Architectual	L: 6', 1"x1", t: 3/16"	$24.78 (need 3)	McMaster
Square Tube	6061	L 6', 1" x 1", solid	$47.33 (need 3)	
Invacare 5180 Foam Hospital Bed mattress	Foam 2 year warranty.	81" x 36" x 5.5"	$149.00	Preferred health Choice
Scissor Table			$160	

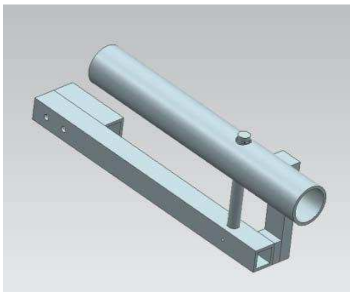
IX. FABRICATION PLAN

Our design requires many parts to be made on a large scale increasing our manufacturing time and material prices. The individual part drawings are in Appendix I with their individual manufacturing plan that includes feeds and speeds and tools and steps needed to shape the part.

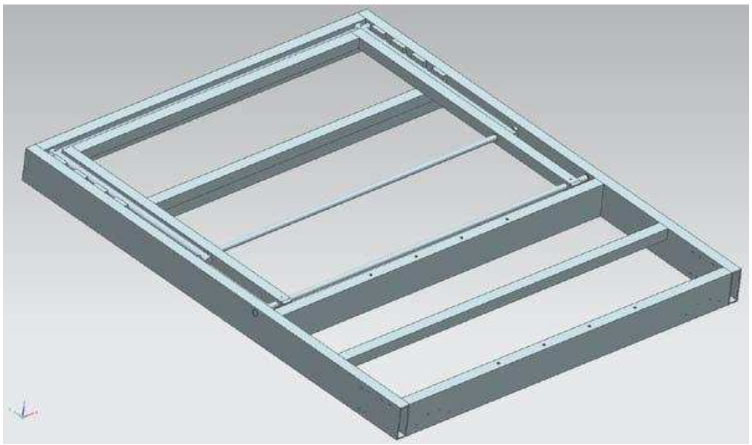
For the assembly, each part for a section was made and then assembled according to what needed to be welded and pinned into place. The first section constructed was the folding panel used for back inclination.

Each of the rods was turned down in order to fit within the welded U frame of 1x1" tubes. The lowest rod is fitted with bearings and retaining ring grooves for insertion into the frame. The other rods are similar with bearings for rotation and fitted with retaining rings. The bearings allow the joins to rotate freely.

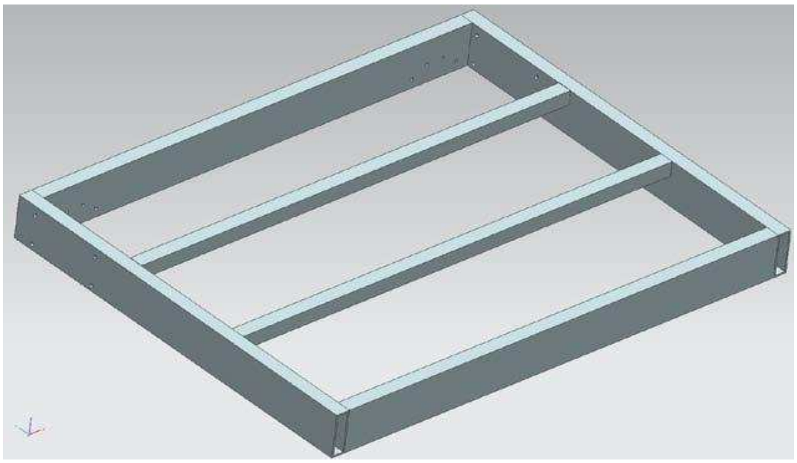
While the back panel rods were fitted, the foot rest were being constructed by fitting bearings into the large tube as well as a dowel pin pressed into the foot rest rod. The stopper and spacer were welded to the 1x1" tube and retaining rings were placed on the bottom and top of the large tube.



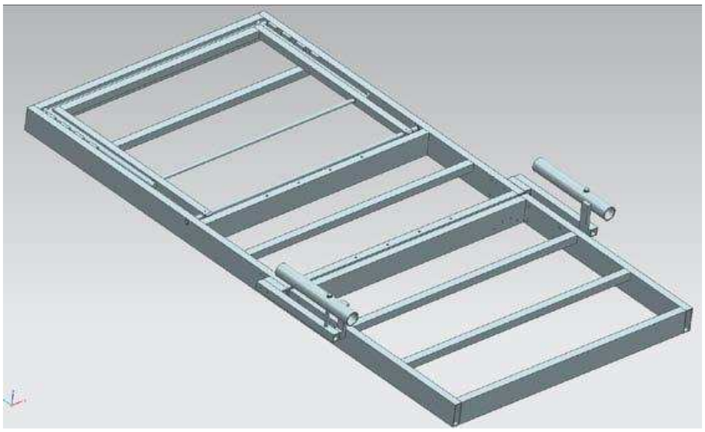
Once the large frame components were fabricated, the back panel was placed in the main large frame for welding everything together.



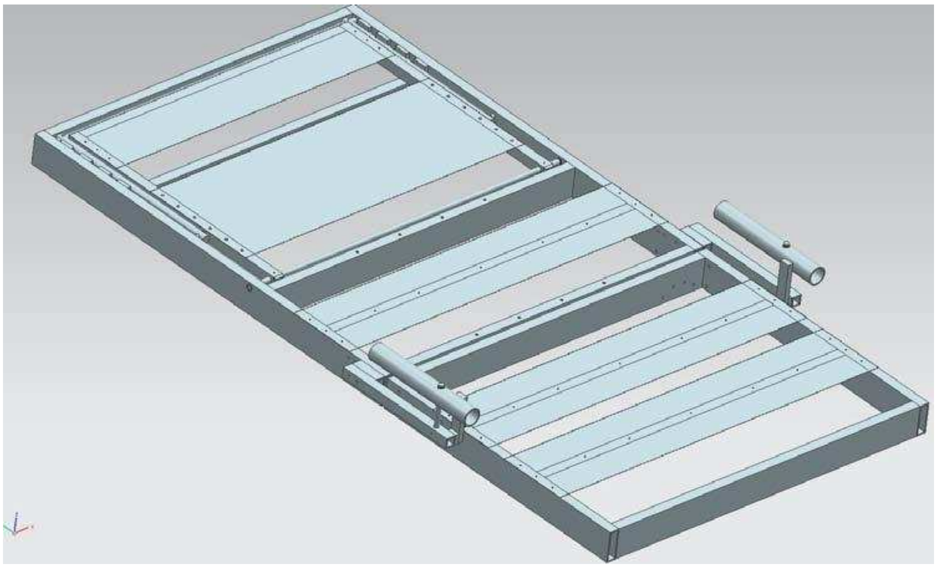
Next the lower third portion of the bed was welded together separately.



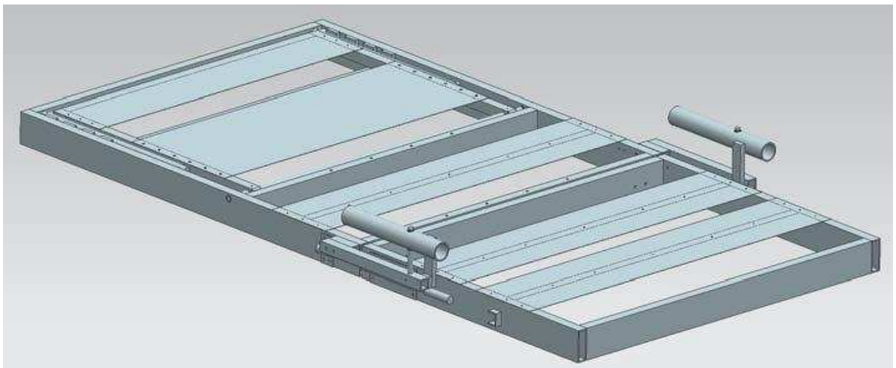
Next the lower third and main frame are connected with two hinges. Then the foot rests are bolted into the sides of the main frame.



Next sheet metal was riveted onto several section of the frame to make sure there were no pressure points causing discomfort to the patient.

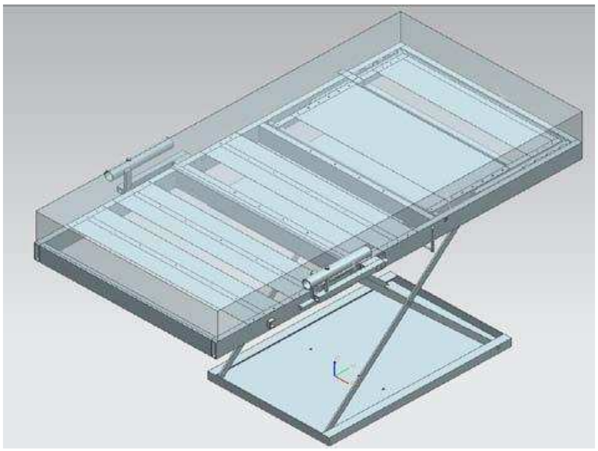


Next four brackets were bolted on either side for a latch bar to hold the lower third upright during labor. Then stoppers were welded on the side to prevent the bar from sliding all the way out from the brackets.



Next the lift would be constructed separately and attached using long bolts.

The handle and cushion for the lower third's edge would be added after the full construction of the metal frame. The mattress in two sections is stuck onto the metal frame with a strong adhesive.



For mass manufacturing, this process would most likely be done by CNC machines in an industrial setting instead of the hand of a machinist. The real quality would have a scissor jack lift made custom for the design specifications.

X. VALIDATION RESULTS

Our prototype was a full scale working model of our final design. We successfully validated our prototype for ease, safety and comfort in using the device.

17 individuals interacted with the prototype and provided their feedback in Likert survey (1=Strongly disagree, 2=Disagree, 3=Neither Agree nor Disagree, 4=Agree, 5=Strongly Agree). Individuals were first asked to transform the bed from labor to delivery position without us giving them instructions on how to do it. They were given a minute to figure out the mechanisms. After that they were trained for a minute on how different parts reconfigure. They were asked again to do the same labor to delivery transformation and were timed again. Then they were asked to get on the bed and lie down while we put them in a labor position and then in delivery position for them to get a feel for the safety and comfort of the bed. The participants then filled out a survey, the results of which are tabulated below:

Question	Avg. Response	Margin of Error*
Felt safe using the device	4	1.5
Easy to operate	3.8	1.4
Felt safe sitting on the bed	4.1	1.5
Easy to operate without instruction	3	3
Easy to operate with instruction	4.5	1.3
Comfortable using all aspects of bed	4.12	1.1
Mattress provided excellent support	4.4	1.5
Overall like the device	4.5	1
Too heavy to operate	1.7	1.5
Uncomfortable to sit on	2	2.5
Difficult to transform without instruction	2.9	2.9

Difficult to transform with instruction	1.6	1.1
Designed to support my stature	3.7	2.6
Time taken for Labor to Delivery transformation (with training)	34.9s	16.6s

*2 x Std. Deviation of all the samples for a 95% confidence interval.

Below is a description of the validation for each user requirement (UR) and a discussion of the survey results:

Safe: (UR: Can withstand 320lb with Xsf=2)
The bed supported a 320lb force without any failure. However, when the entire weight was added to the ends of the beds, the bed was tipping over. This was expected as the mechanical lift that was used for the prototype had a smaller base as compared to our ideal requirement. This caused higher moment arms and tipping occurred. We do not see this problem occurring in our ideal design.

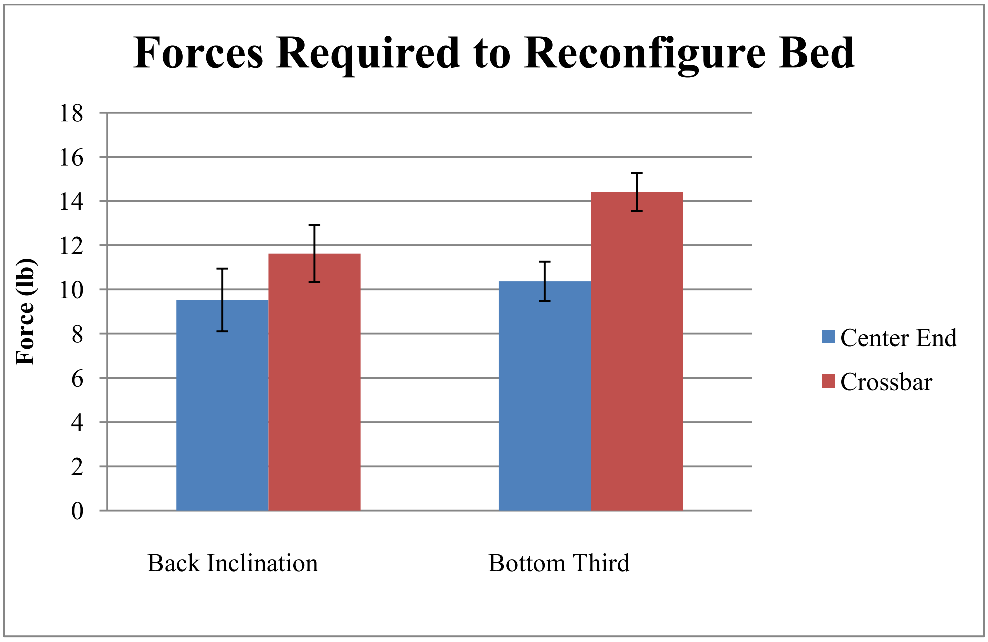
In the survey, participants gave an average rating of 4.0 for overall safety feel and 4.1 for the perceived safety while sitting on the bed.

Inexpensive: (UR: <$1000)
The total cost of the prototype was $XXX, which included the cost of purchased materials as well as materials acquired from the machine shop. However, this does not cover labor charges but we expect the final price to remain similar since the material cost will come down in large scale manufacturing.

Quick and Easy to Adjust: (UR: ≤3 steps or ≤30 s requiring ≤22lbs force)
The bed is transformable in three steps by inclining the back rest, removing the latches and turning the foot rest in delivery position. The latter two steps can be done standing at the same spot so we did not need to physically connect both the latches. Two separate latches also increase safety since, if someone unlatches one of them by mistake, then the second one will still be there to prevent any accidents.

The average time taken by the participants for labor to delivery transformation was 34sec with less than a minute's training. This is very close to our requirement of 30s and we expect this average to go down by a more elaborate training. Participants agreed that it was easy to adjust with training but there was not a clear agreement that the device was easy to adjust without prior training. This is not a problem since any medical equipment of this kind will have some minimal training associated with it before usage.

To validate the force required for transformation we measured the force required to lower the bottom third of the bed and lift the back inclination system. This was done using a force gauge at the side of the frame and also at the center of the frame (from the front). The result is shown in a bar graph below:



As can be seen from the graphs the maximum force required is well within the 22lb user requirement we had.

Adjustable Lumbar Support : (UR: 0-70º from horizontal)

The grooves on the frame for back inclination enables the bed to lie 4 positions ranging from horizontal (0º) to 70º

Adjustable Vertical Height

Although we demonstrated the proof of concept for our height adjustability using a off the shelf scissor lift table, the table wasn't made to our specifications and it did not reach the 38" maximum height. This specification will be tackled in our ideal design by making our own lift table.

Leg Separation/Access to Pelvis: (UR: >30-45º from the body's bilateral plane of symmetry)

We measured the leg separation of the participants using a protractor. The separation angle was the angle between the two thighs when the feet were rested on the foot rests. We got a minimum angle of 35º and it went up to 120º for some people when they rested their feet on the outermost parts of the foot rests. Higher the range the better it is for the attendant, so we did better than we expected on this parameter.

Patient Comfort

The average user rating for 'excellent mattress support' was 4.4 which demonstrates that the users really appreciated the comfortable feel of the foam. We got an average rating of 2 when we asked the same question is an opposite manner, i.e., if mattress was uncomfortable to sit on.

Long Lifetime and Easy to Clean

We will not test for the longevity since our prototype has components that will not be in the final ideal design. We also could not validate the time taken to clean since the vinyl covering we used was very thin and it ripped while we carried out other tests on the prototype.

XI. DISCUSSION AND RECOMMENDATIONS

The inspiration behind our design was maternal health. As maternal mortality is the health indicator with the greatest disparity between developed and developing nations, we wanted to contribute to the improvement of maternal health through design innovation. One way in which we identified we could contribute to improving the safety, comfort, and efficiency of childbirth in resource-setting was through the construction of a labor and delivery bed equipped with the specific functions necessary for this setting.

A formal design process was utilized to assist in the creation of our device. Over four months our team generated qualitative end-user requirements, and translated such data into quantitative engineering specifications. Upon better understanding the needs of our end-users, various group brainstorming exercises were performed to generate concepts, and different strategies were employed to down-select to our final design. Engineering analysis was performed for initial validation of our design. Once a design was selected, our group began selecting materials and performing initial engineering analysis to assess the validity of our design.

Cultural practices and normative social behaviors were influential in the design of our labor and delivery bed. Health care attendants have limited time per patient, thus our design must be quick and easy to adjust. Upon preliminary validation we found the average time to adjust our bed from the labor to the delivery position after given 1 minute worth of instruction was 35s (n=14). Further, the device can be transformed in four steps. Based on our interviews with health care attendants in Ghana, such measurements satisfy the user requirements identified.

Our current prototype has many strengths. First, it is designed to provide support for the full spectrum of female body frames (constructed to support up to 95% of women). Second, the adjustable nature of the bed from a labor position to a delivery position minimizes the transfer of patients in the ward, therefore increasing the efficiency of the labor ward as health care providers are not burdened to clean multiple beds per person, and traffic of patients blocking the aisle is reduced. Perhaps most importantly, the total cost of materials for our device was around $500. Cost is a significant barrier which limits the medical devices a resource-limited hospital can purchase. With the aim at making our device accessible to the maximum number of end-users, a device around this price point would have a greater likelihood of being implemented. Additional preliminary validation supported further user requirements such as “easy to operate,” and “comfortable.” Force gauges measured the amount of forces necessary to adjust the back and the lower third of the bed and revealed no more than 14lb of force was necessary to complete either task. Further users rated the ease of operating our device on average 4.4/5 (n=10) and comfort of device scored on average 4.3/5 (n=10). Such data suggests these features of our device will be acceptable to our target end-users.

Future work on this project will include further design iterations and in-depth engineering analysis. Given the scope of our undergraduate design course, we had approximately 4 weeks reserved for manufacturing. Therefore, there are elements of our prototype which will be modified in the upcoming semester. Namely we will be focusing our efforts on constructing a mechanical scissor lift, instead of using the commercially available hydraulic foot pump scissor lift. Additionally, our feet support rods of our prototype did not withstand the maximum force a woman can push (300lb) and we will need to develop another mechanism for locking the rods in place such that they provide the requisite support for women of all sizes.

To assure our design is acceptable to our target end-users we will travel back to Ghana in March with a scaled down version of our prototype. We will interview health care workers to receive feedback on our design and this information will be influential in the redesign phase of our device. Market analysis is currently being performed to assess the viability of our product into the global market.

XII. CONCLUSIONS

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XIII. ACKNOWLEDGEMENTS

This work was supported by the University of Michigan Minor in Multidisciplinary Design: Specialization in Global Health Design. We would like to thank the Komfo Anoyke Teach Hospital (Kumasi, Ghana) and the following affiliates of the University for their support in this endeavor: The College of Engineering, Center for Entrepreneurship, and African Studies Center. Additionally we would like to recognize the National Collegiate Inventors and Innovators Alliance.

Special thanks to our mentors and consultants: Dr. Kathleen Sienko, Dr. Anthony Odoi, Dr. Frank Anderson, Dr. Jason Bell, Amir Sabet Sarvestani, Alice Zheng, and Joseph Perosky. Their knowledge and contribution was largely beneficial and influential throughout the design process.

XIV. BIOGRAPHY

Tiffany Chen is currently a senior majoring in Mechanical Engineering with plans to graduate in April 2011. Before college she played violin for 15 years, and was a member of the high school swim team. Though she's from Troy, Michigan she is in love with New York Yankees baseball. What she enjoys about mechanical engineering is how it applies to so much of daily life. She has especially enjoyed the design process—starting from nothing and no background knowledge and ended up with a final working prototype with an expertise in the subject. Working on this project, especially because she has an interest in science and medicine, has been an enjoying and fulfilling experience. After graduation, she is currently deciding between working in industry, pursing a master's degree, or applying to medical school.

Gillian Henker is one of the mechanical engineering students working on the team designing a multifunctional labor and delivery device (team 10). She was born in Seattle, WA but spent 14 years in Pittsburgh, PA growing up. Her father's entire family is constrained to the state of Wisconsin while her mother's family resides in a suburb south of Boston. She feels like a part of her is from all of these places since she spent significant parts of her life in each. Her interest in mechanical engineering comes from the idea that she sees it as a way to make an impact in the world. The rest of her family is in the nursing field but she has no strength in emotional matters of that kind. She feels that mechanical engineering allows for some creativity behind the math and logic instead of memorization and strict procedure. In the future, she hopes to do some type of extensive volunteer work either here in the USA or abroad. Farther than that she has few ideas about where she wants her career to go. She loves dancing with Ghanaian men.

Carolyn Payne is a senior in the Political Science and Women's Studies department. Her professional aspirations include attending medical school and specializing in Women's Health. She hopes to use her skills to improve women's access to reproductive health care services domestically and globally. Though not an engineer, she was delighted at the opportunity to contribute to maternal health via this Global Health Design Project and feels her skill set offers a unique perspective to the engineering dominated team. Aside from medicine, Carolyn's other interests include traveling and exercising. She enjoys spending time with family and is looking forward to the upcoming birth of two nieces! Though born and raised a Buckeye, Carolyn couldn't be happier at the University of Michigan and is thankful for the unique opportunities this institution has provided.

Vishal Sonthalia is an international student from India in the Biomedical Engineering Dept. and will be graduating in April 2011. He was born in eastern India, grew up in the west, went to high school in the north and did the first two years of college in the south. He sees himself as a sensitive and very optimistic person and often find it easy to look at things in life from different perspectives. He has an eye for photography and is an avid day-dreamer! This project is really relevant to his goal in life of making a difference somewhere in an entrepreneurially exciting way. He believes that learning the whole bottom up approach to the design- build- test process will be very instrumental in developing products and services in the future and analyzing people's needs in general. After graduating, he would like to get some industry knowledge in the US, eventually starting a new business setup back at home in India.

XV. APPENDICES

APPENDIX A: SURVEYS DISTRIBUTED

Figure A1. Survey I

Name: ______________________________ Position in Hospital: ___________________________

We are designing a multifunctional labor and delivery bed and would like your input on the importance of the following features.

Features of Labor and Delivery Bed	Least Important 1	Less Important 2	Neutral 3	More Important 4	Most Important 5
Cost					
Longevity					
Easy to repair					
Patient comfort					
-- Mattress comfort					
-- Stirrups					
Transporting the bed					
Adjustable back inclination					
Adjustable pelvis inclination					
Collection of bodily fluids					
Quickly Cleaned					
Handles for labor and delivery					
IV Stand					
Holder for patient charts					
Manual power to adjust bed					
Electrical power to adjust bed					

What additional features do you think are important or necessary for this bed?

Please provide your contact information so me may contact you for further information.

Phone Number: ______________________ Email Address: ___________________________

Figure A2. Survey II

Name ________________ Position in Hospital ____________

Please rank the following characteristics of a convertible labor and delivery bed in order necessity from 1-7 (1 most important – 7 least important)

______ Back Inclination

______ Adjustable Height of Bed

______ Stirrups

______ Fluid Collection System

______ Pelvic Inclination

______ IV Stand

______ Equipment Stand

What are the steps you would take to convert a labor bed into a delivery bed?

APPENDIX B: MARKET ASSESSMENT PLAN TO BE CONDUCTED BY OUR BUSINESS ASSOCIATE ALICE ZHENG

Market Assessment Plan

- "Customer discovery model" will be the primary framework used to assess market feasibility for this product
    1. Product hypothesis
        - Key product benefits [engineering team]
        - Delivery schedule [engineering team]
        - IP issues
        - Cost of ownership [engineering team] – includes training, replacement of parts, etc.
        - Dependency analysis – what economic conditions, process/behavior modifications will be needed for the product to be successful? How will we measure this?
    2. Customer hypothesis
        - Defining different customer types – day to day, influencers, recommenders, economic buyers, decision makers
            - Need to research role of NGOs, multilateral aid organizations (UNICEF), unilateral aid (USAID), and government in equipment purchasing in different levels of gov't and private institutions
            - Need to understand procurement process – how are decisions made and by whom?
            - Need to understand organization structure of KATH and similar hospitals, and the relationship between the different customer types (for example, day to day vs. decision makers)
        - How aware are customers of the "need" we are addressing, and what have they done about it? How "mission-critical" is this "need"?
            - Likely **Latent need –**customer is aware of the problem, but not in active search of a solution (**Active need)** and have not attempted to create their own solution **(Has a vision)**
        - What do they do/use now?
            - Operating capacity, workflow in Ob/Gyn, current products [researched for KATH from this summer – what about other types of institutions?]
        - How to justify the return on investment (ROI)
            - How is the hospital financed? Would use of this device reduce costs (less infections?), improve efficiency? Provide intangible benefits like improved customer satisfaction?
            - What global health/social impact, and how to measure?
    3. Distribution channel and pricing hypothesis
        - Current distribution channels for medical equipment
        - Current spending on labor/delivery beds, especially similar products
            - How frequently are beds purchased?

  - At what price would half of customers be willing to buy?
  - Would product sell easier stand-alone or as part of package?

  4. Demand creation hypothesis
  - Marketing strategy, potential partners, key industry influencers/recommender contact list
  - **Political environment:** Understand key trends in the field – MOH focus areas? Ghana Health Service focus areas? Global health donors?

  5. Market type
  - **Resegmenting an existing market** on basis of being a "low cost provider" of existing features (as opposed to **existing market** or **new market**)

  6. Competitor hypothesis [engineering team]

- Additional background analysis
  1. Market sizing – how many deliveries are done in hospitals like KATH per year? What about smaller/lower-tier hospitals? Rural hospitals? Other institutions that may use labor/delivery beds? How many beds does each of those types of institutions have? What is the turnover rate for such beds?
  2. Regulatory processes for medical products – MOH?
  3. Medical device market landscape – who are the key players in Ghana?

APPENDIX C: QFD

System QFD

Project:	Multifunctional Labor and delivery device
Date:	Sept 19 2010
	Input areas are in yellow

#	Technical Requirement	1	2	3	4	5	6	7	8	9	10	11
1	Number of Steps to Adjust											
2	Target Price											
3	Height from Floor	3										
4	Angle of Back Support	3										
5	Leg Angle from Center	3										
6	Volume of Fluids											
7	Lifetime		9			1	1					
8	Time to Clean	1		1	1	3	9					
9	Time to Adjust	9		9	9	9			3			
10	Width of Area for patient positioning								3			
11	Strength of Materials		3			1	3	9	3		1	
12	Degrees of Motion	3		3	3	3			1	9		

Survey Legend	
A	Current product
B	Competitor B
C	Competitor C

Technical Requirements

#	Customer Needs	Customer Weights	Kano Type	Number of Steps to Adjust	Target Price	Height from Floor	Angle of Back Support	Leg Angle from Center	Volume of Fluids	Lifetime	Time to Clean	Time to Adjust	Width of Area for patient positioning	Strength of Materials	Degrees of Motion
1	Afforadable Cost	4			9					3					
2	Quick and Easy to Adjust	4		9								3			3
3	Optimal Height	4		9		9								1	
4	Back Inclination	3					9								1
5	Leg Separation	3		3				9							3
6	Access to Pelvis	3		1		3		9				3			
7	Fluid Collection	2				1			9			3			
8	Longevity	2			3					9					
9	Patient Comfort	3					9						9	9	9
10	Safety	2				3						1		3	
11	Easy to Repair	1		1	9					9				9	
12	Quick to Clean	1									9	3		3	1
	Raw score			85	51	53	54	54	18	39	9	32	27	49	52
	Scaled			1	0.6	0.62	0.64	0.64	0.21	0.46	0.11	0.38	0.32	0.58	0.61
	Relative Weight			16%	10%	10%	10%	10%	3%	7%	2%	6%	5%	9%	10%
	Rank			1	6	4	2	2	11	8	12	9	10	7	5
Requirement Benchmarking	Best in Class														
	AVE														
	Worst in Class														
	Kano			L	L	L									
	Direction														
	Technical Requirement Units			steps	$	inch	degrees	degrees	L	Years	min	sec	inch	kg	degree
	Technical Requriement Targets			3-4	1000	29.5-33	0-70	45	6	>5	1-5	30-60	>30	200	1-3

Customer Opinion Survey

1 Poor	2	3 Acceptable	4	5 Excellent

APPENDIX D: WHOLE CONCEPT GENERATION

Figure D1: Concept Table

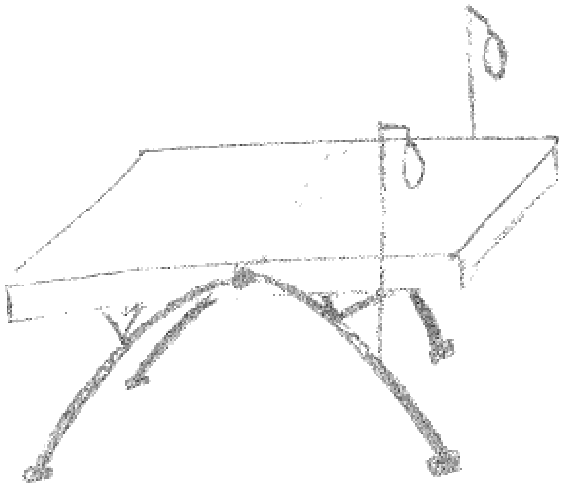


Figure D2: Concept Inflatable Bed

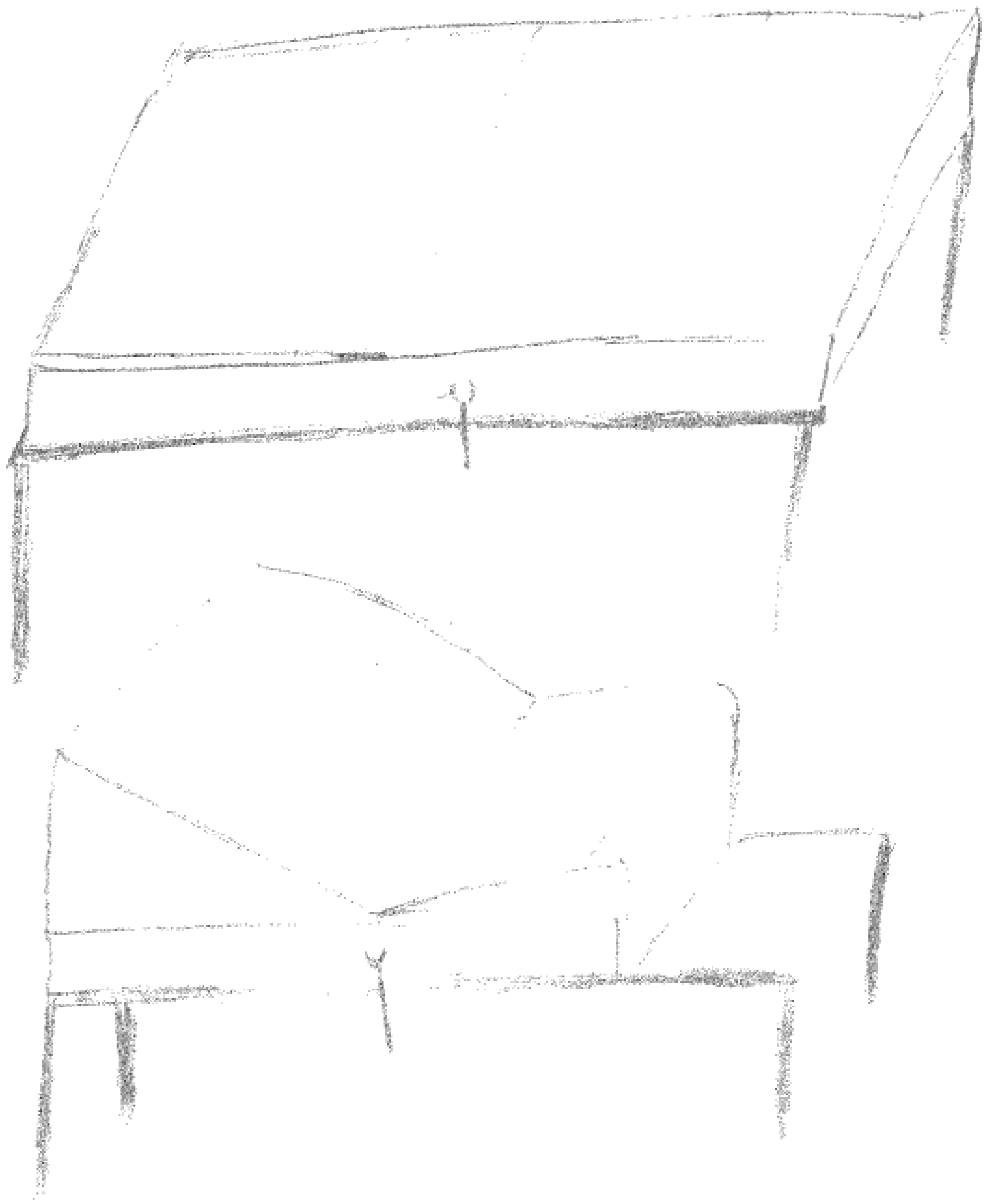


Figure D3: Concept Pyramid

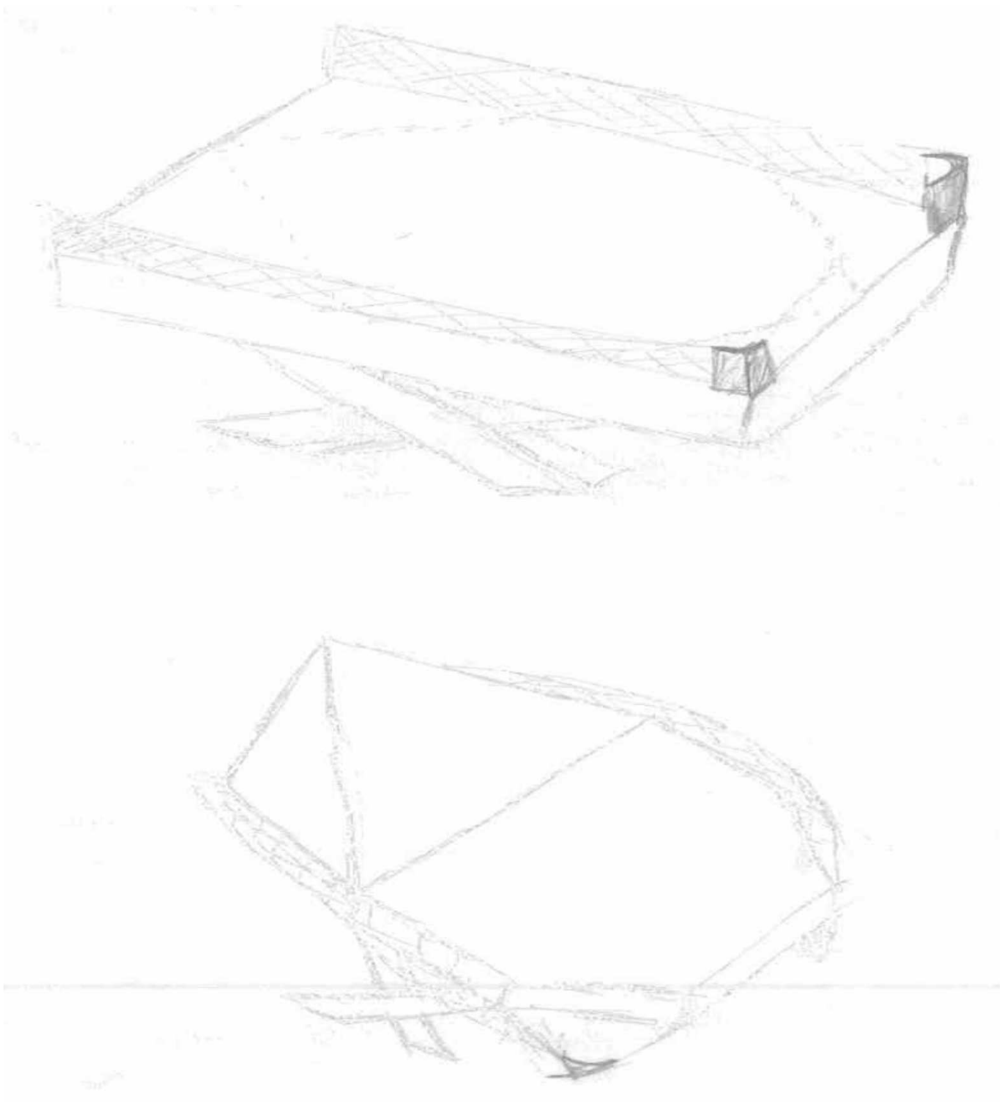


Figure D4: Concept Reconfigurable foot table

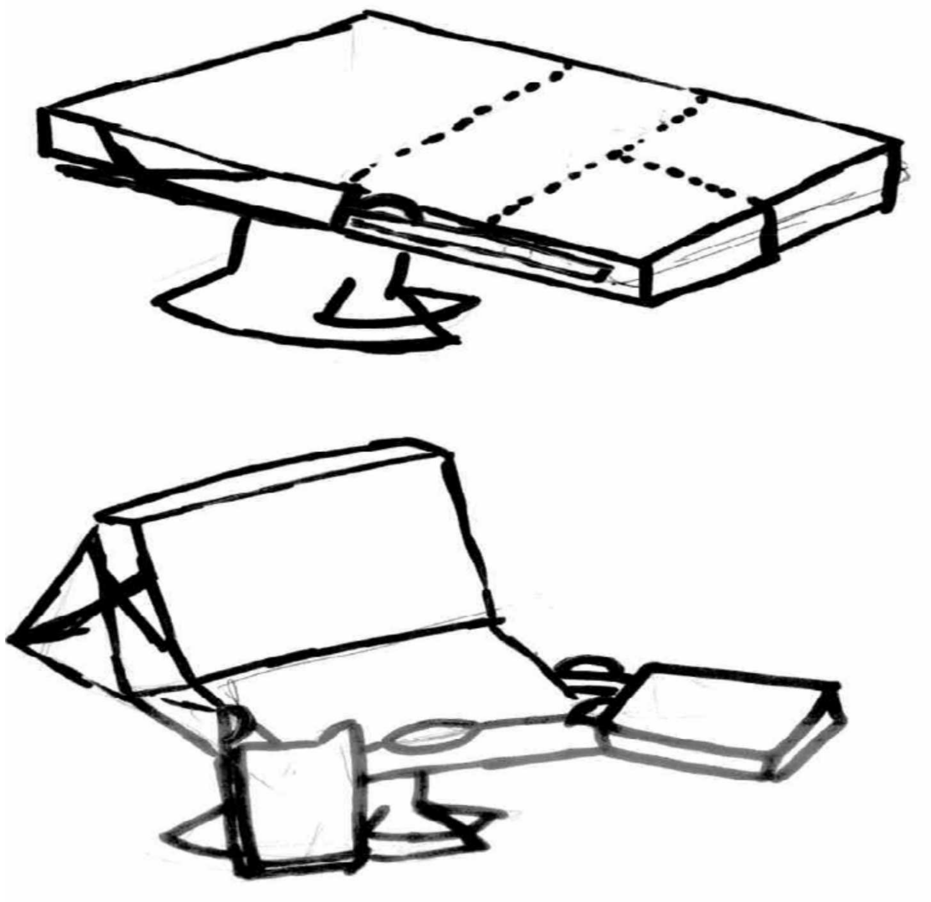


Figure D5: Concept Crib Recliner

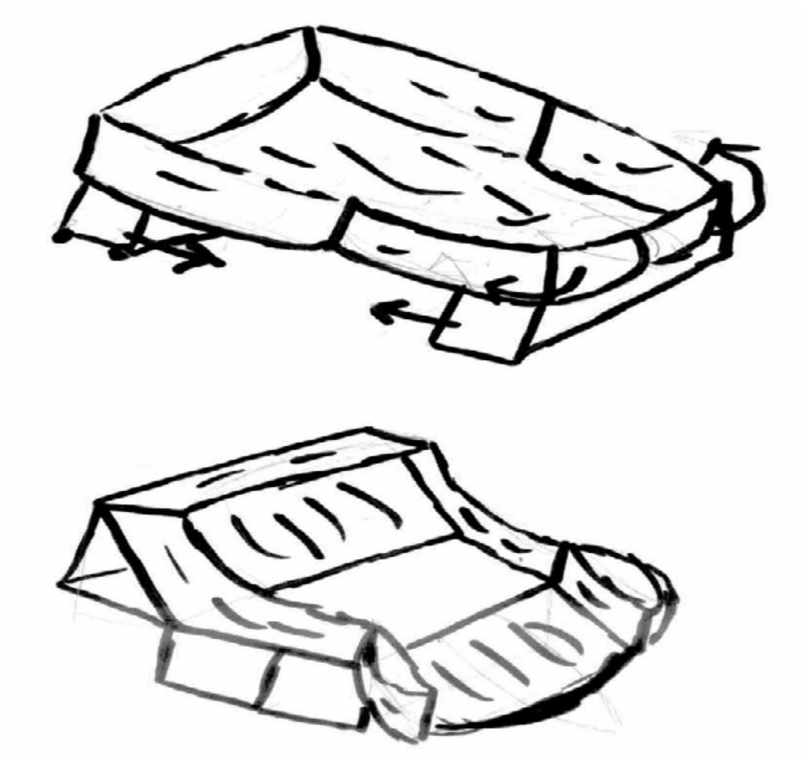
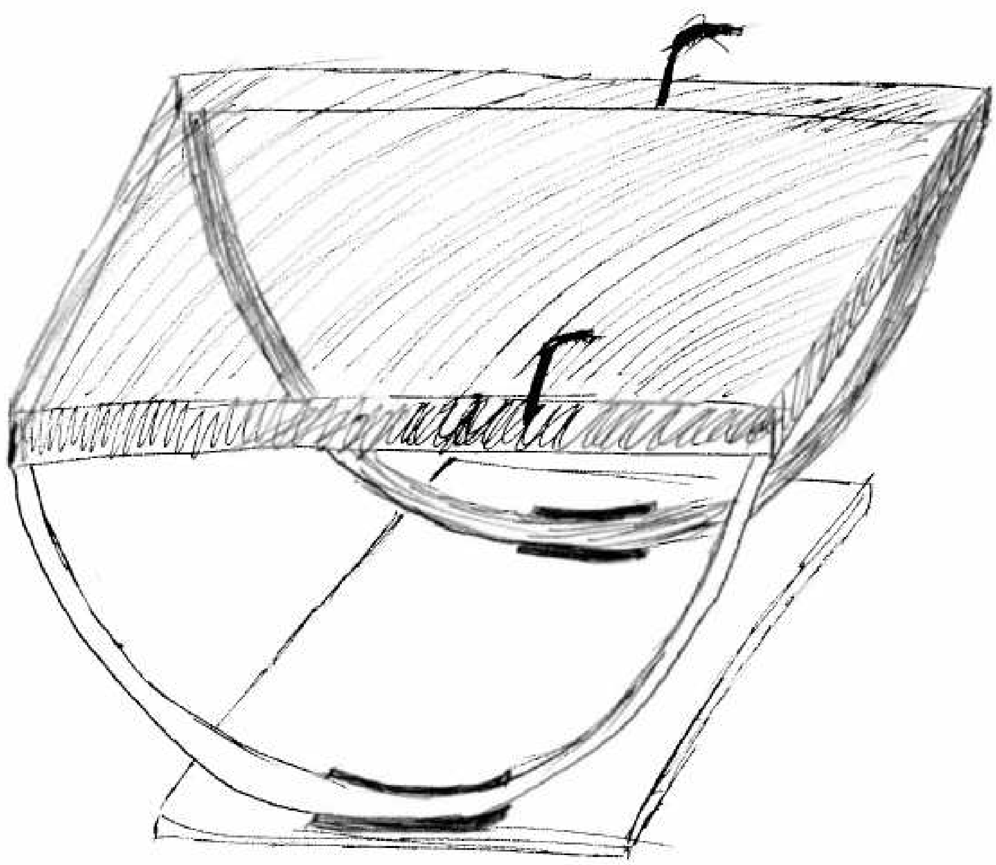


Figure D6: Concept Rocker



APPENDIX E: COMPONENT BRAINSTORMING

Figure E1: Leg Separation concepts

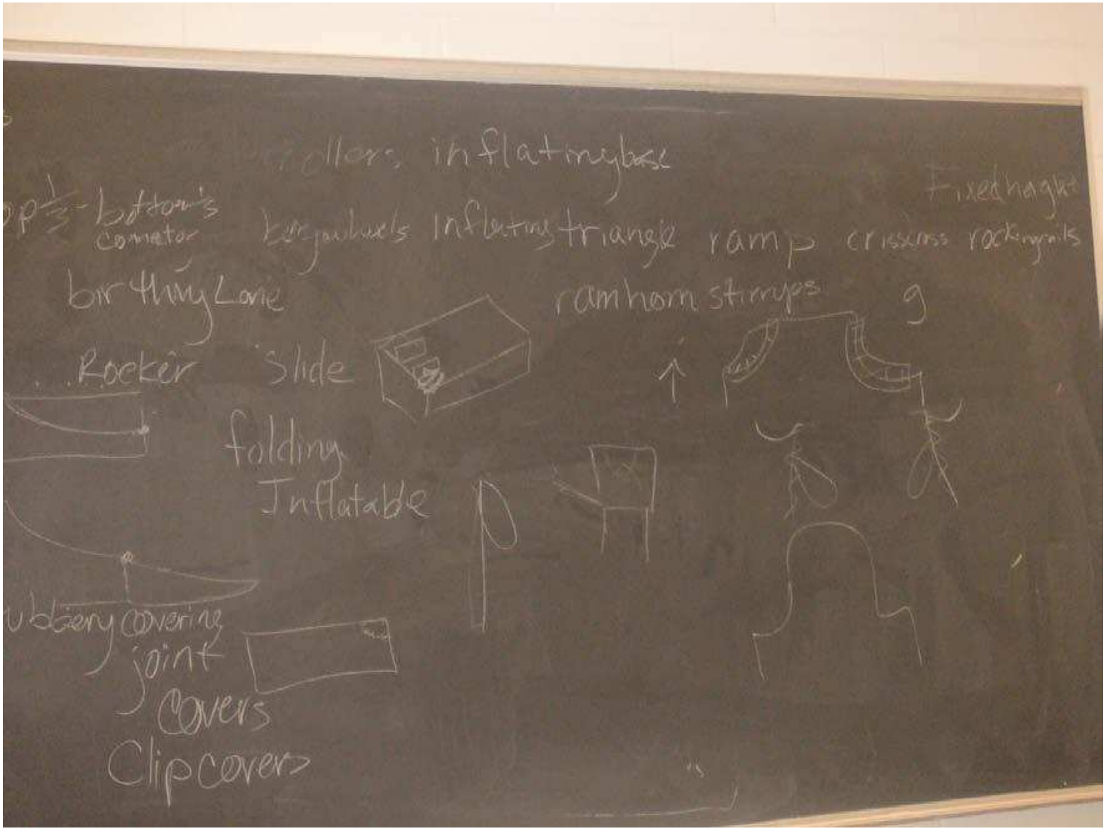
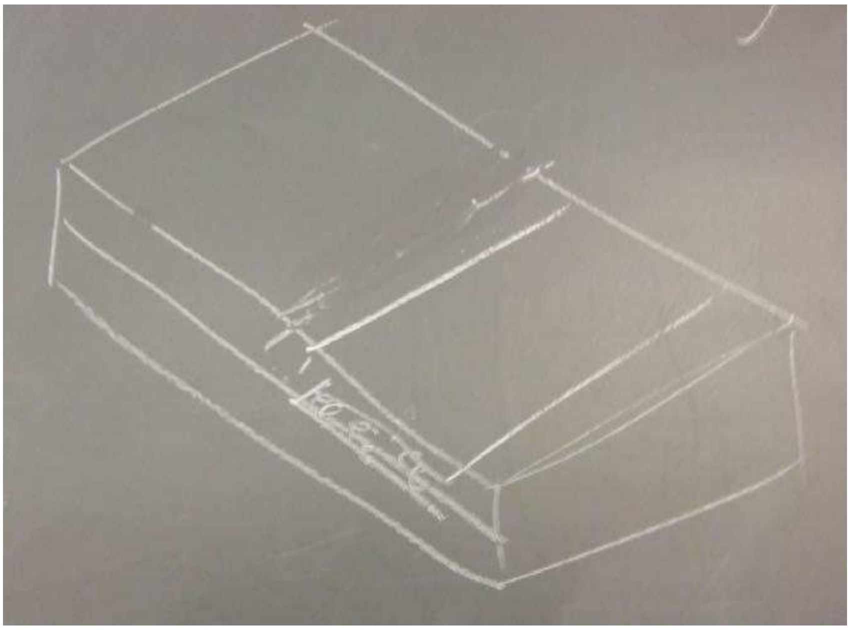


Figure E2: Springs for height adjustment concept



APPENDIX F: GROUP BRAINSTORMING

Figure F1: Whole concept 1

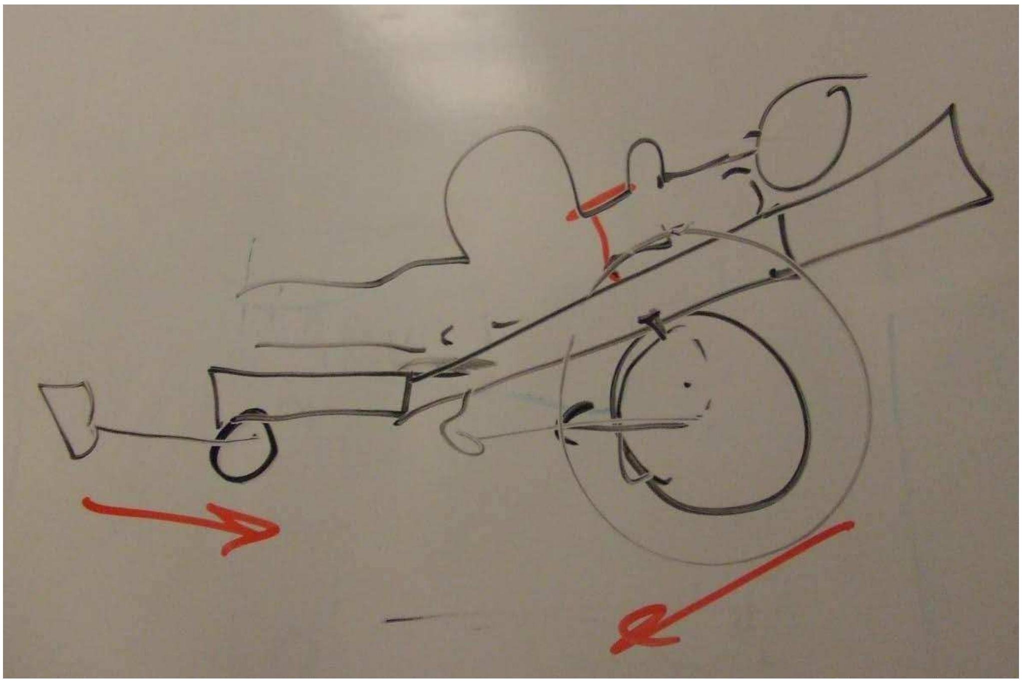


Figure F2: Leg separation brainstorming

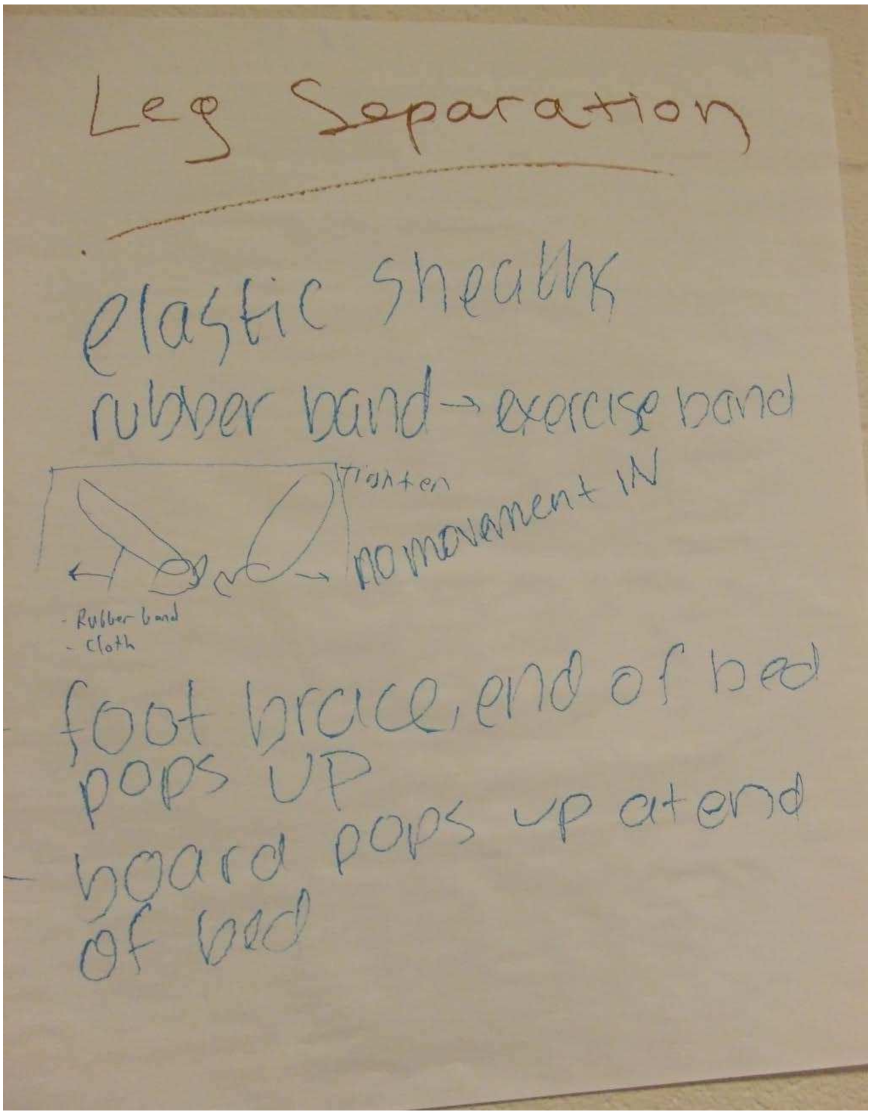


Figure F3: Height Adjustment

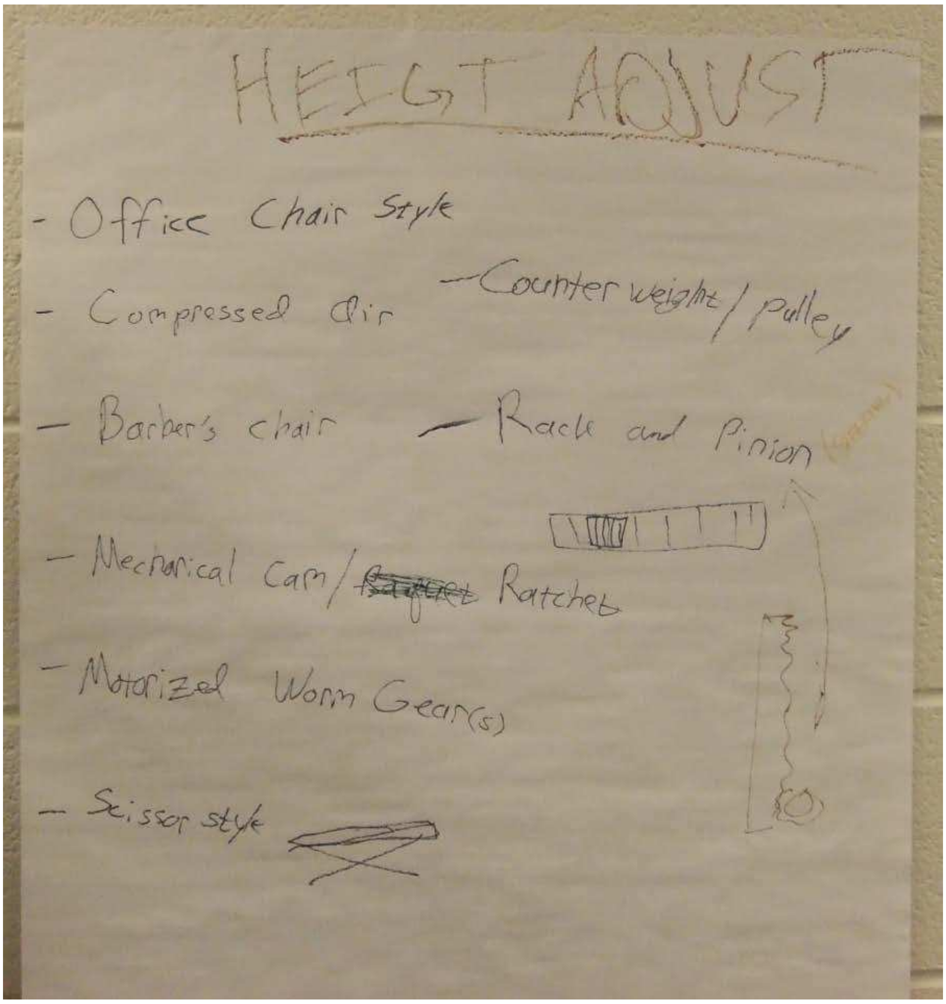
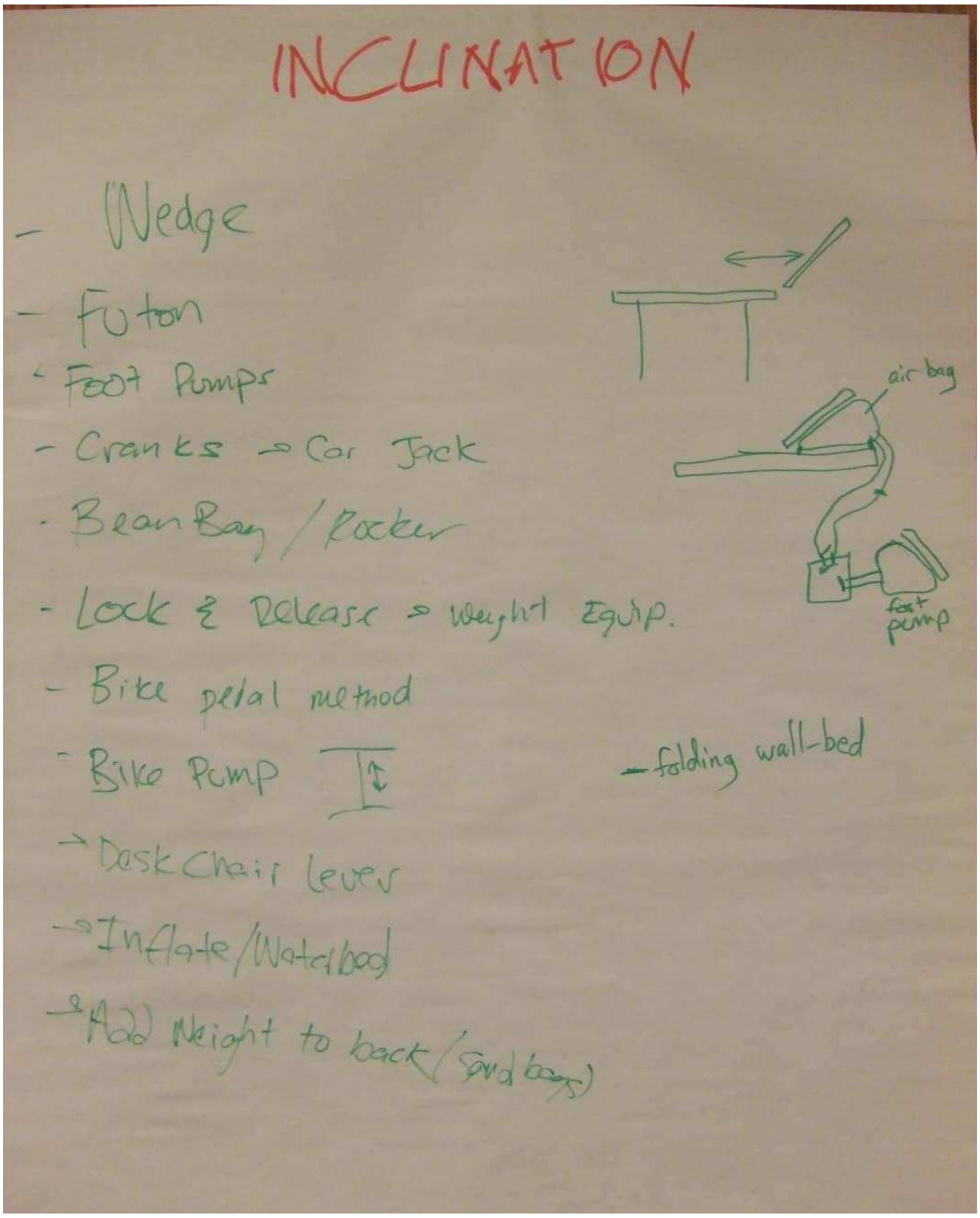
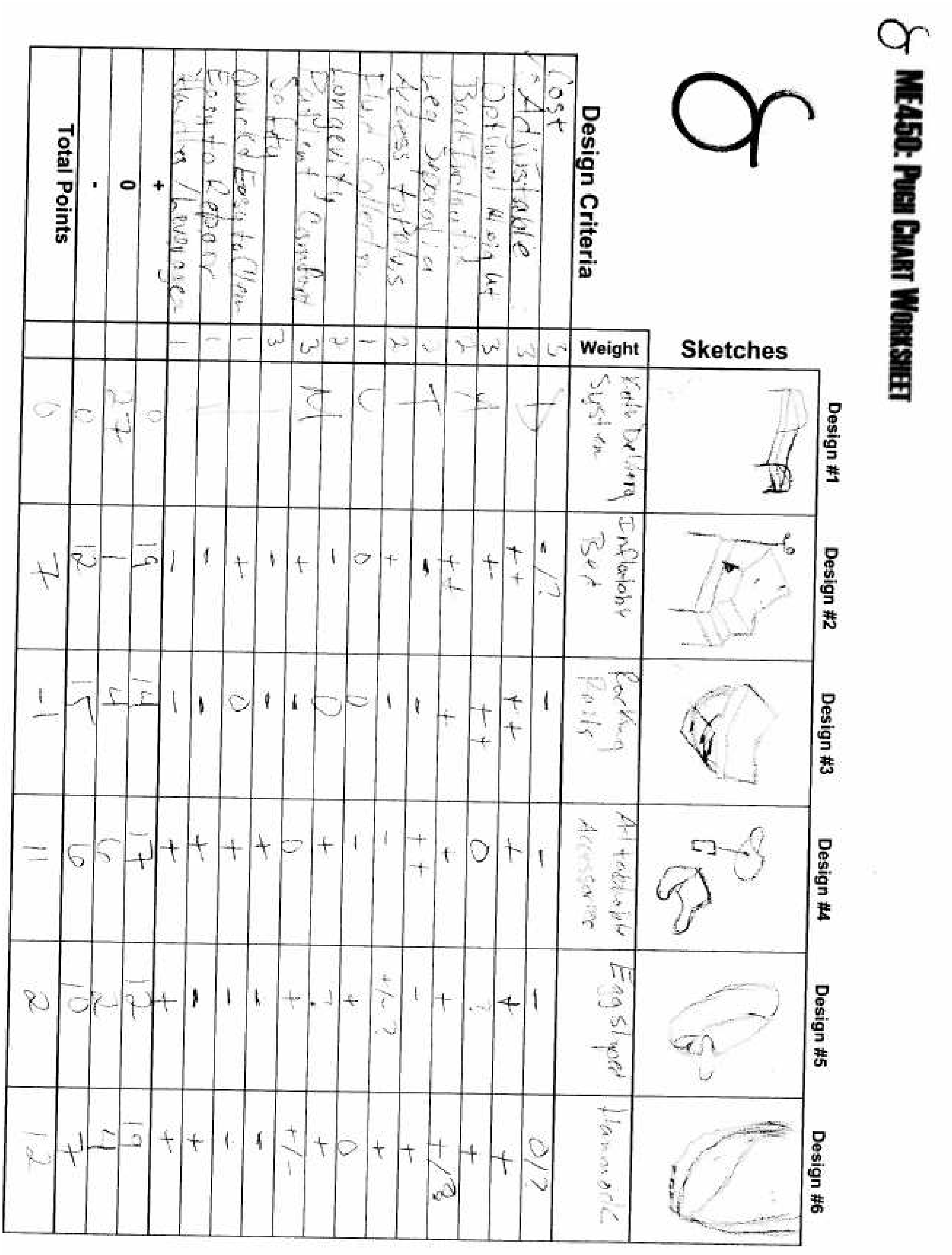


Figure F4: Back Inclination



APPENDIX G: PUGH CHARTS

Figure G1: Pugh Chart 1 Whole concepts



APPENDIX H: ENGINEERING ANALYSIS FROM DR 2

Every user requirement our team generated has an associated engineering specification. These engineering specifications need to be met within our chosen concepts. Thorough engineering analysis of our alpha design will reveal where changes need to be made in order to meet every one of our engineering specifications and thus meet every user requirement and the identified need statement.

Safety

Our top user requirement, safety, requires our design have a safety factor of at least 2 and to be able to withstand a load of at least 263kg. Being a medical device, safety is enforced by the FDA and most likely other organizations. We plan to conduct theoretical failure analysis to anticipate and prevent and chance of yield and fracture by using the following equations:[xc]

$$\sigma_{1,2} = \frac{\sigma_{xx}+\sigma_{yy}}{2} \pm \sqrt{(\frac{\sigma_{xx}-\sigma_{yy}}{2})^2 + \tau_{xy}{}^2} \text{ (Eq1)} \qquad K_I = FS_g\sqrt{a\pi} \qquad \text{(Eq2)}$$

Equation 1 identifies the principles stresses in the material that should be less than the yield strength of our material that we select. Equation 2 provides the fracture toughness needed to prevent failure by fracture. The safety factor will help to determine which material has a yield strength high enough to withstand this target weight. To test these values, our team plans to perform static load tests on various parts of our design.

Low Cost

After safety, our device must be low cost at a total price of less than $2000. We will determine an estimated cost by researching several vendors of stock materials that fit within our design parameters. Also we need to estimate how much the manufacturing cost would be in a resource limited setting in order to make an accurate price approximation. To calculate this price, we will need basic math arithmetic.

Quick and Easy to Adjust

The user requirement quick and easy to adjust specifies that the design have less than three steps to adjust from the 1st stage of labor to the 2nd stage of labor or less than 30sec with 22lbs of force for each step. To determine these target values our team plans to use rigid body kinematics and kinetics dynamics. The following equations are some that might be utilized to meet these specifications:[xci]

$$F=m*a \text{ (Eq3)} \qquad v = \omega \times r \text{ (Eq4)} \qquad a = \alpha \times r \text{ (Eq5)}$$

$$KE=1/2*I*\omega^2+1/2m*v^2 \text{ (Eq6)} \qquad PE=\int m*g*dh \text{ (Eq7)} \qquad PE_{Spring}=1/2k*x^2 \text{ (Eq8)}$$

All of these equations will enable us to determine the force needed to move different components of our design as well as the speed that these actions can be completed. These measurements can be validated with a force gauge to determine the amount of force needed to operate a feature and by timing a user operating the components.

Back Inclination

The back inclination is an important requirement for the comfort and positioning of the patient. When inclining the back portion of the device, the maximum angle should not exceed the 70°. This target value can be determined with rigid body rotation equations above. When modeling our concept, we discovered that too steep of an angle could increase the amount of force needed to incline the back. To validate this requirement, a load will be placed on the back portion and a force gauge will push on the mechanism to adjust the back to a 70°.

Optimal Height of the patient

The birth attendants need the height to adjust a range of 3-4" in order to have proper access to the patient's pelvis. Our device should lower enough for a patient to climb on safely but high enough for the birth attendants to provide care during the delivery process. Our design will be analyzed using static loading and dynamics of rigid bodies. The following governing equations of static mechanics:[xcii]

$\frac{d\theta}{dx} = {}^{M}/_{EI}$ (Eq9) $\epsilon = {}^{\delta}/_{L}$ (Eq10) $\sigma = {}^{F}/_{A} = {}^{My}/_{I}$ (Eq11)

Equation 9 describes the second derivative of deflection that could occur while adjusting the height of the device. Equation 10 and equation 11 are the general strain and stress equations which will determine the displacement and forces on our height adjustment mechanism. If these factors lead to possible failure, a stationary height may need to be chosen. To validate the change in height, a patient size load will be applied to the design and a tape measure will take the first height and then a second height after the device is raised.

Leg Separation

Secure leg separation is a key component to the ensuring that the birth attendant has access to the patient during delivery. The engineering specification requires the legs to be 60-90° apart from each other. Using geometry and anthropomorphic data, we will be able to calculate this range for women in the 5th -95th percentile. The range in sizes of women will drive our design concept in addition to subject testing for comfort while subject's legs are separated. Geometric measurements on the device will verify that the angles are correct. Physical model will aid greatly in making decisions about what fits the form of a woman and what is uncomfortable.

Longevity

Lifetime of a device is critical for low resource setting that value low cost investments that last. Several failure modes are linked to wear over time. If the lifetime of the device is long enough, an investment will be worthwhile for the procurement office. The target for this device is 5 years of use in a major medical facility with a high turnover rate. Fatigue and creep are the two main failure mechanisms for the environment we are looking to meet the need of. The following governing equations describe creep and fatigue:[xciii]

$\dot{\varepsilon} = \dot{\varepsilon_0} * ({}^{\sigma}/_{\sigma_0})^{n}$ (Eq12) $\sigma_{ar} N^{a}{}_{f} = C_1$ (Eq13)

Validating these estimates presents a great challenge to our team. Conservative theoretical analysis at this time looks to be the only option to get a secure estimation. Anything over the minimum lifetime requirement is a great driver in the over design.

Access to Pelvis

For the safety of the patient, the birth attendant must have proper access to the pelvis for delivery. The engineering specification identifies the shortest length the attendant should be from the pelvis. This length is the 5th percentile of American women's arm lengths as the minimum. To validate this specification, we will have a variety of subjects reach into the pelvic area from where the attendant will be positioned in addition to doing geometric calculations with anthropomorphic data. Models of the device will allow us to compare the dimensions to the anthropomorphic data of the potential attendants.

Patient Comfort

Patient comfort was the most difficult user requirement to quantify into engineering specifications. We determined that the thickness of the patient surface should be 5" thick consisting of a medium to hard foam. The overall width of the patient surface should be at least 30" wide to allow for the patient to be in a variety of positions. Subject testing will ensure the most accurate assessment of patient comfort. We will be looking into surveying a wide range of materials and asking people what is comfort to them.

Models of our design will be presented to a variety of subjects and they will be asked what looks and feels comfortable to them. Our target would to have over half the subjects rate our device as comfortable.

Fluid Collection System

The fluid collection system for our device depends heavily on the supplies already within the low resource setting. Other features of the device will aid in the fluid collection design. Fluid dynamics will be important to calculate the area needed to contain all the fluids during the delivery stage. The Bernoulli equation will be the governing equation to calculate the area where the fluid will be flowing.[xciv]

$$\frac{1}{2}(\rho v^2) + \rho g z + p = const \text{ (Eq14)}$$

This calculation will be a conservative estimate and not entirely accurate because of the ideal assumption being made.

Quick to Clean

The process of cleaning our device has a time limit of no greater than 5 minutes for engineering specifications. Also anti- corrosive materials should be used in the manufacturing because of the harsh bleaching agent Parazone. A model showed that having fewer exposed crevices could streamline the cleaning process. Subject testing will be used to validate the amount of time it will take to clean the surfaces that come into contact with the patient. For selecting materials, cleaning products will be used on a variety of materials to test for corrosive side effects. The material which stands up the best to the harsh cleaner would validate the use of that material.

Easy to Repair

Another user requirement that has been difficult to quantify is the easy to repair. This requires all the pieces of our device to have the ability to be machined by the maintenance staff at the major medical facility in the resource limited setting. All the tools we have access to for prototyping our device were seen in a resource limited setting. We will keep track of the manufacturing time for making our own prototype and from that judge whether or not our target has been met or not. We will have to note that we are not expert machinist and that this will be an over estimate.

IV Stand

The IV stand should be 44.5” tall from the labor bed height of 29”. Static mechanics and geometric analysis will be used to design the shape of the rod. A variety of loads will be placed on the rod to validate the theoretical analysis and make sure the target load can be met. Models of the IV stand will be part of the validation testing as well as getting a physical stand to measure and place within the design.

Pelvis Inclination

For after the procedure the attendants would prefer to have the option to incline the pelvis 15° above the horizontal or below. The engineering analysis needed to analyze this specification includes the previous mentioned equations on statics and dynamics mechanics. The force needed to move the pelvis those 15° would need to be analyzed modeling rigid body rotation in equations 3-8. To validate this specification, geometric measurements will need to be taken as well as a force gauge being used with a static load on the device to represent the patient. Static loading analysis will need to be conduct at the level position of the pelvis and the inclined positions of the pelvis in order to ensure the safety of the patient.

Container for supplies

The container for supplies has a specified volume requirement for all the different tools necessary for the birthing process. To analyze this requirement, basic geometric and other mathematical concepts will be used to create an optimized shape to fit within the design. Validation for the container will be measuring the outside of the models created and based on these model containers the target volume will be modified.

Leverage for hands of patient

Leverage during the deliver process was used by many patients giving birth. The engineering specification prescribes that the leverage component be no more than 27.8" from the head of the device so that women in the 5th percentile will be able to reach it. The leverage mechanism will be analyzed using static mechanics where a load is applied and all the stresses and strains are analyzed for possible failure as in equations 1-2. To validate these findings, a dynamic load in the direction that the patient would pull or push will be applied to the device. Varying shapes will be modeled to look for the optimal design in stability and rigidity.

Light Source
The light source should be at least 60 Watts for adequate light during suturing of the patient after delivery. Based off the equation $P = VI$(Eq 15), we can calculate the current and resistance necessary to power a 60W light source.[xcv] We will validate this by inserting a standard 60W light bulb into the source and looking at the brightness of the light.
Transportable

At the bottom of the user requirements is transportable. The engineering specification that is associated with transportable is the amount of force needed to lift, push or pull the device is less than 88lbs. To obtain this target, static and dynamic motion analysis will be calculated using the governing equations 3, 6-8. To validate these calculations, a force gauge will be used to measure the force needed to lift, push or pull the device.

DESIGN DRIVERS

There are several different design drivers that could change the form and function of our design as we move forward into design review 3. We focused in our alpha design on four key features that are the most important to meeting the top user requirements. These features were back inclination, optimal height, leg separation and access to pelvis. The top feature of this list is back inclination which relates the most to patient comfort and optimal positioning for delivery. Optimal height is the number one feature for the birth attendants because of their comfort and the safety of the patient. Leg separation and access to pelvis are related to each other in many ways so there is the potential for the two to be considered one driver themselves. All of these features are the most critical to the design.

A main design driver looking into the future is the ability to manufacture this prototype within the time a lot for this class. Manufacturing a project of this scale could restrain our team to looking at the key user requirements instead of the entire list. Simplicity in the design will ensure easy manufacturing but there is still the necessity for the design to meet the most user requirements possible.

The main difficulty in our design is the amount of manufacturing that needs to take place to make a fully constructed prototype. Time is against us with the many features and components within each of the main four features. Fully designing every single detail in the CAD model will also be difficult to accomplish in the given time frame because of the scale of our design. In addition to making the prototype, validating our prototype will require various forms of subject testing which needs a large number of volunteers.

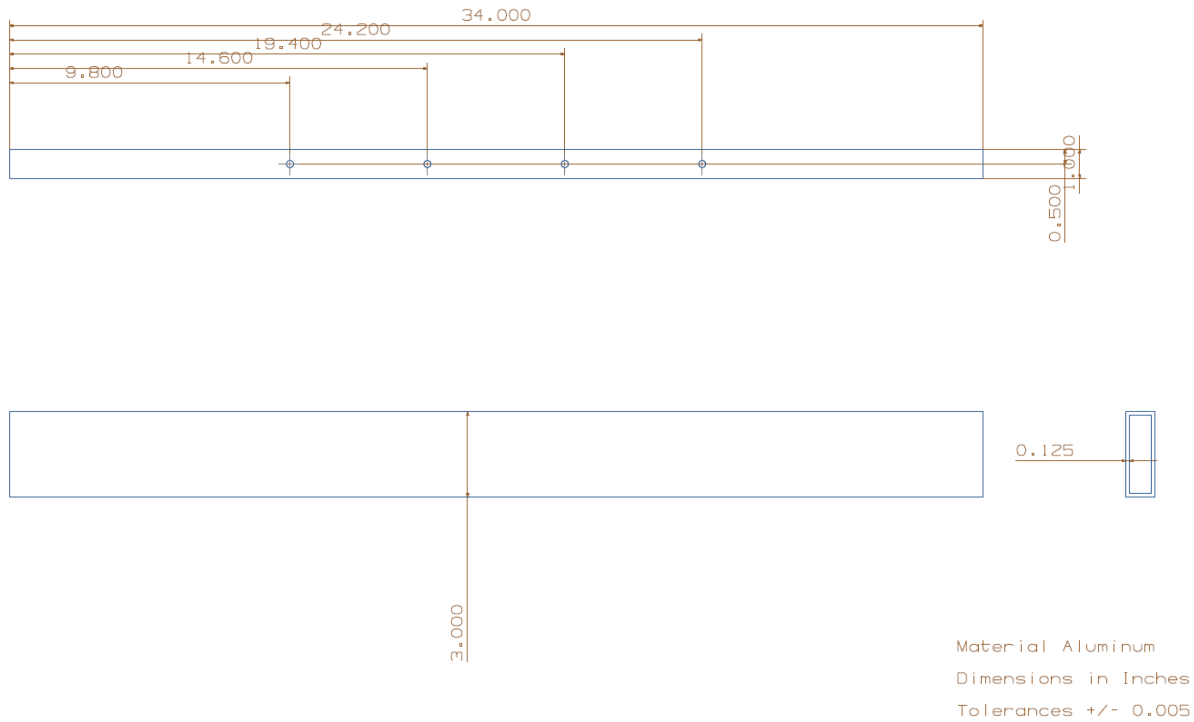
Some of the major problems expected are finishing the entire project in the timeline of this class and staying under the allotted budget given. Previous projects similar to this one have shared shortcomings with our team and the main failure was lack of manufacturing time. Even before the manufacturing stage, we are continuing to develop our concrete mechanisms and having difficulty making them tangible.

We plan to try and make solid a CAD design early in order to gain permission to start manufacturing earlier than other team in the class. This way time will not be the limiting factor on our design. During the CAD modeling, we will probably work on an Adams model as well to work out several varieties of mechanisms to verify which ones are realistic and which do not work.

Some technical assistance might be needed during the construction of our prototype pertaining to welding different parts together. Other than assistance in manufacturing no technical assistance is or special equipment is necessary at this time.

APPENDIX I: DETAILED FABRICATION PLANS AND PARTS LIST

Figure I1: Pelvis Tube



Pelvis tube

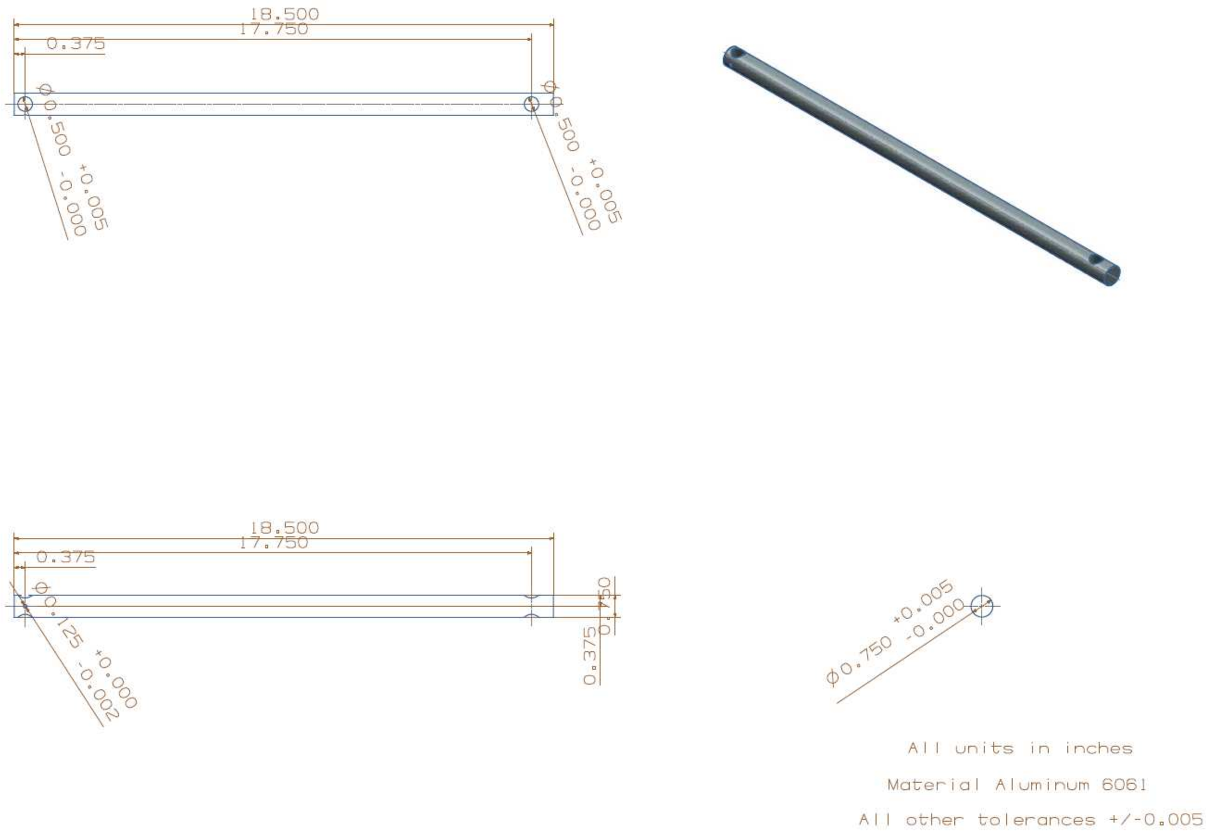
-Band saw 1”x3” square aluminum tubing

-Square-off end with 1/2” end mille running 1600 fps

-Center drill all eight holes on mille 1100 fps

-Use ¼”drill bit to use the drill press for four holes

Figure I2: Adjustment Rod Fabrication Plan



Adjustment rod x2

-Band saw stock to within half an inch

-Square off the piece with a 1/2” end mille 1600fps

-Center drill and drill 1/2” hole on mille

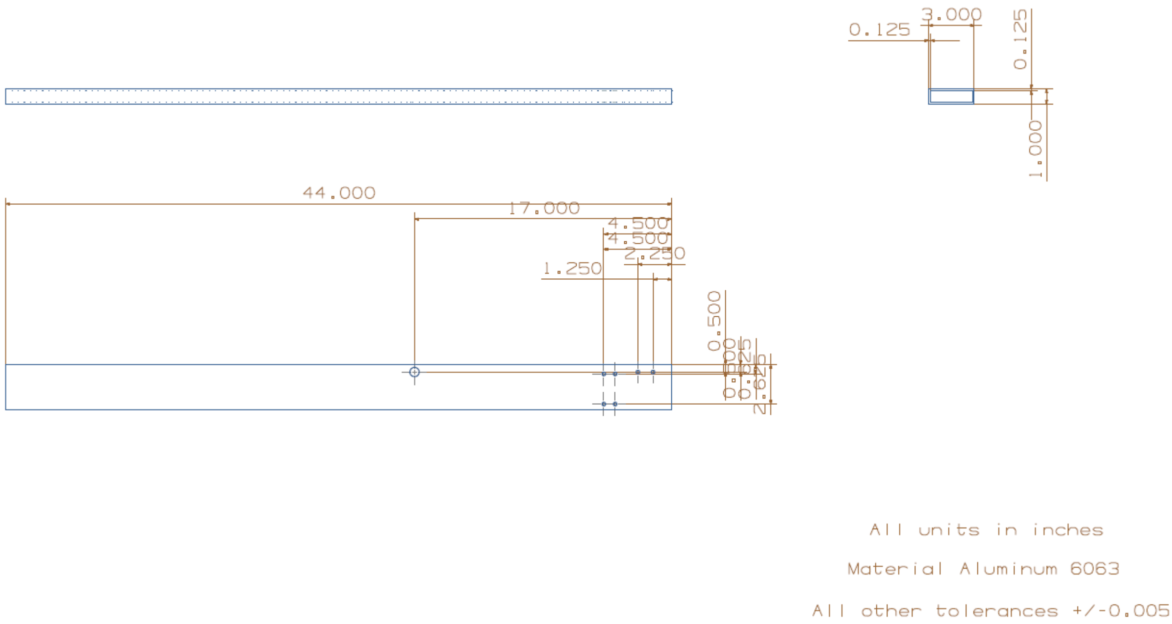
-Use drill press with ½”drill bit respectively for each of those holes

-Center drill for 1/8” hole on mille

-Use 7/64” drill bit in mille to under drill hole

-Use 1/8” reamer to ream hole

Figure I3: Lengthwise tube Fabrication Plan



Lengthwise tube x2

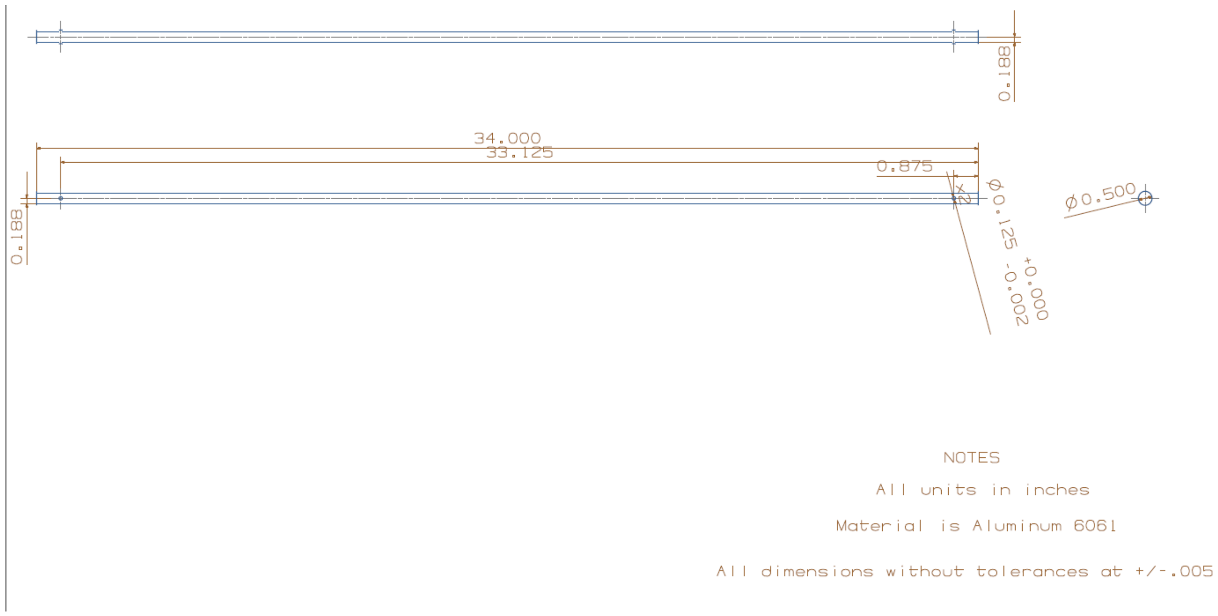
-Band saw stock to within one inch

-Square off in the mille using 1/2” end mille 1600fps

-Center drill all holes on the mille 1000fps

-Use ¼” and ½” drill bits for the respective holes on drill press

Figure I4: Peg Rod Fabrication Plan



Peg Rod

-Band saw rod to within 1” of final length

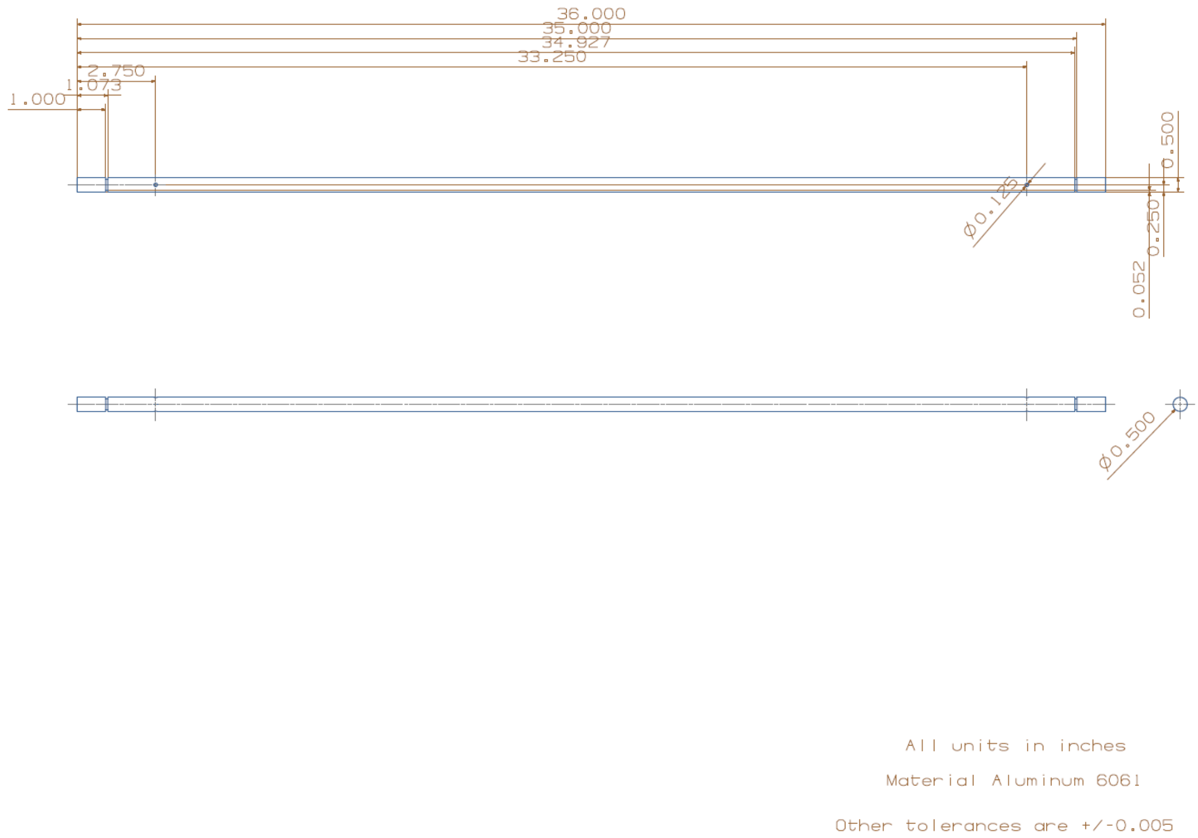
-Square off the end with a 1/2” end mille 1600fps

-On mille center drill two holes on the end

-Under drill with 7/64” drill bit on mille

-Ream with 1/8” reamer each hole on mille

Figure I5: Rotation Rod Fabrication Plan



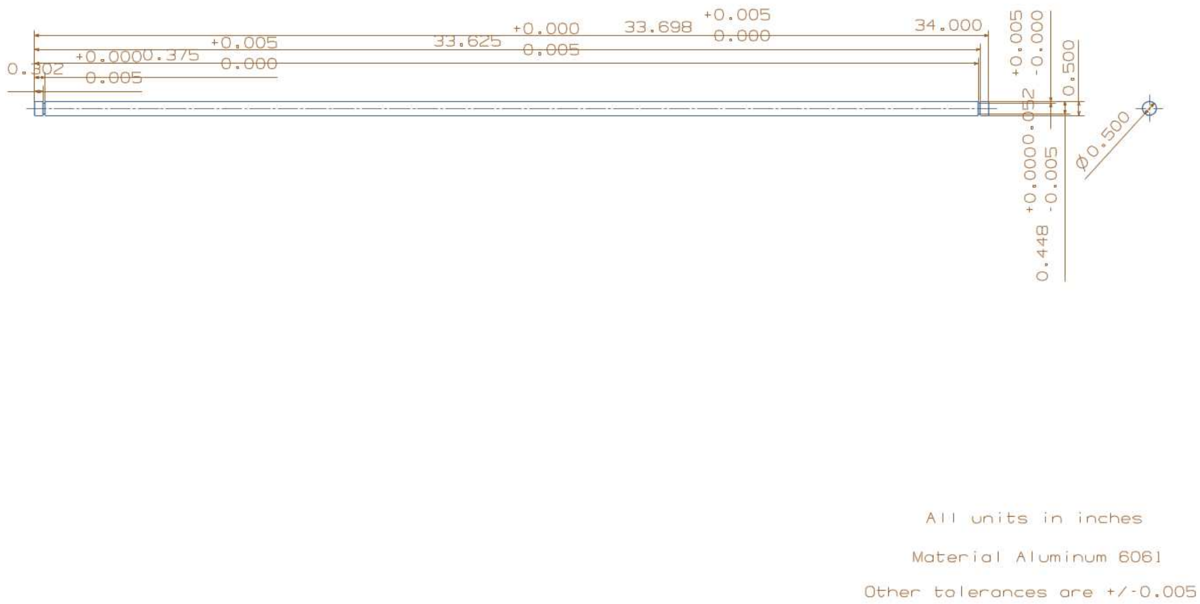
Rotation Rod

-Band saw rod down to within 1" of desired length

-Square off the end with 3/8" end mille

-Turn in lathe to acquire two grooves for E clips

Figure I6: Connection Rod Fabrication Plan



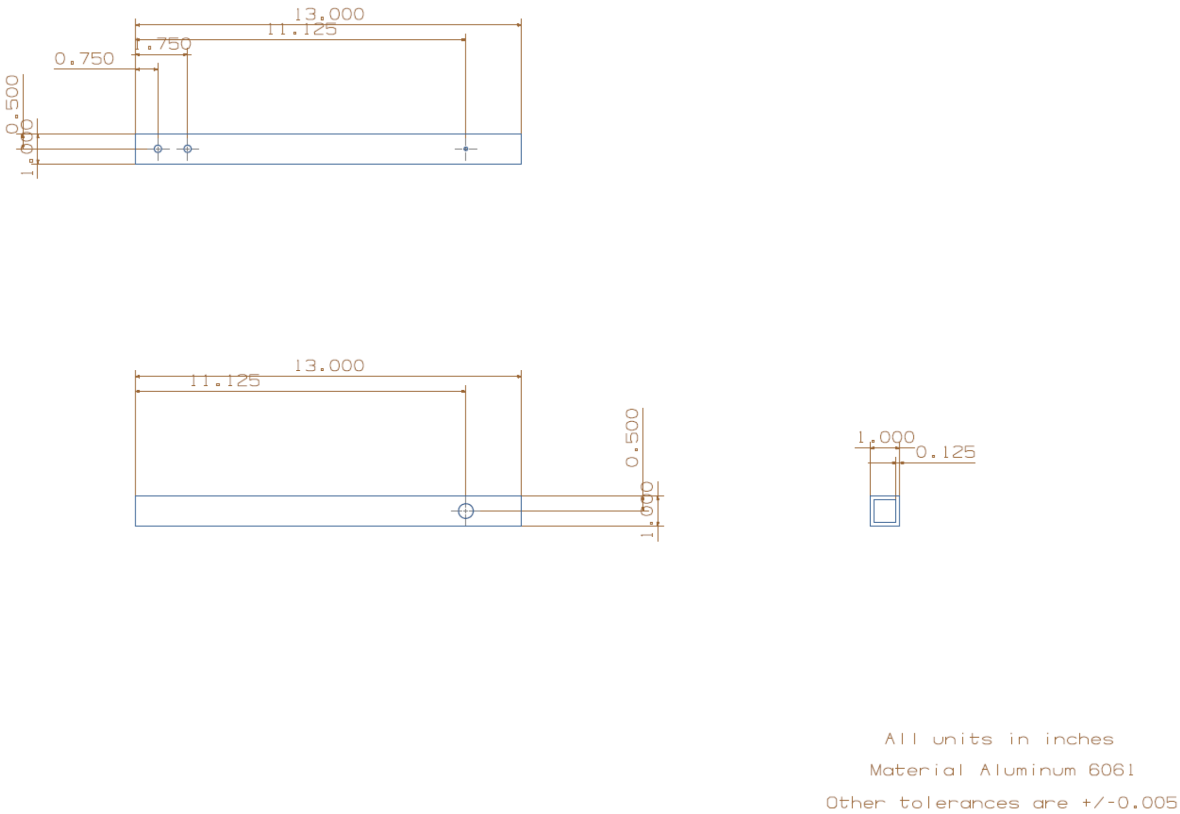
Connection Rod

-Band saw to within an inch of desired length

-Square off with 3/8" end mille

-Turn in the lathe to depth of .052" for placement of E clips

Figure I7: Foot Rest Tubes Fabrication Plan



Foot Rest Tubes x2

-Band saw piece within 1” of desired length

-Square off piece with 3/8” end mille

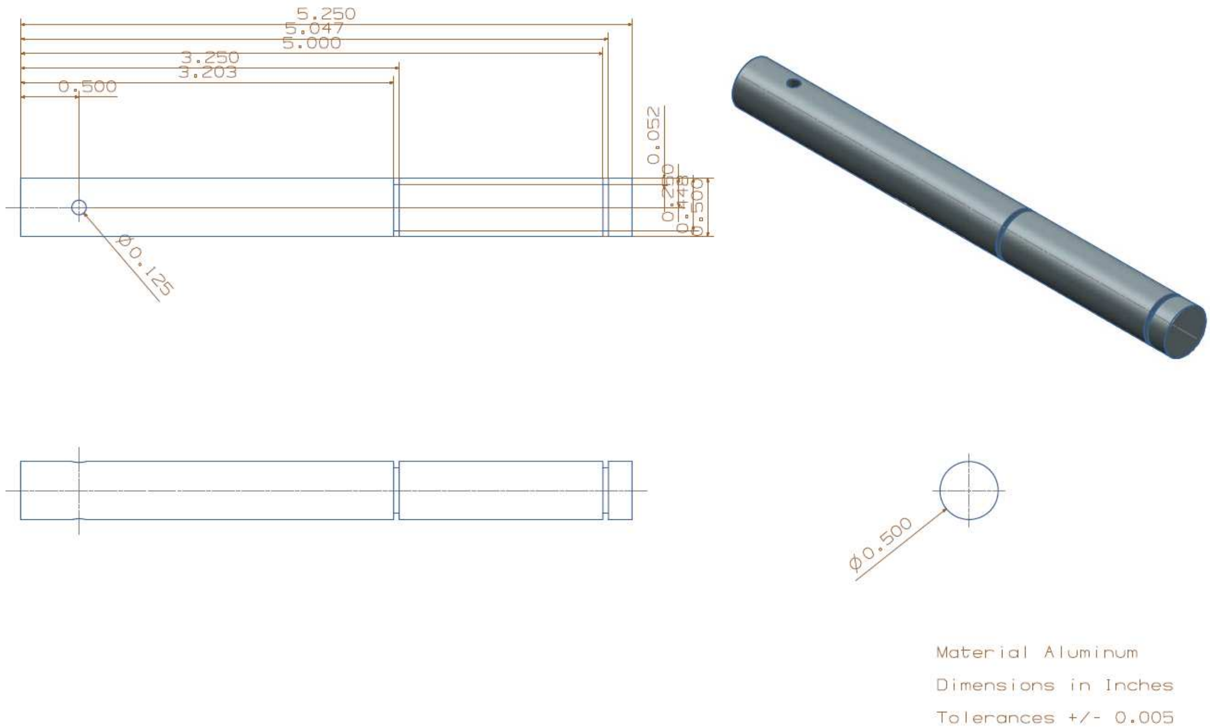
-Center drill all four holes on mille

-Use drill press for both ¼”holes and ½”hole

-On the mille use 3/32” drill bit to under drill hole

-Use 1/8” reamer to ream hole on the side

Figure I8: Foot Rest Rod Fabrication Plan



Foot Rest Rod x2

-Band saw round piece with in 1” of its desired length

-Square off the piece with a 1/2” end mille 1600 fps

-Center drill hole at the end of the piece

-Under drill hole with 7/64” drill bit

-Ream with 1/8” reamer in the mille

-Turn in the lathe to a depth of 0.060 for an E-clip

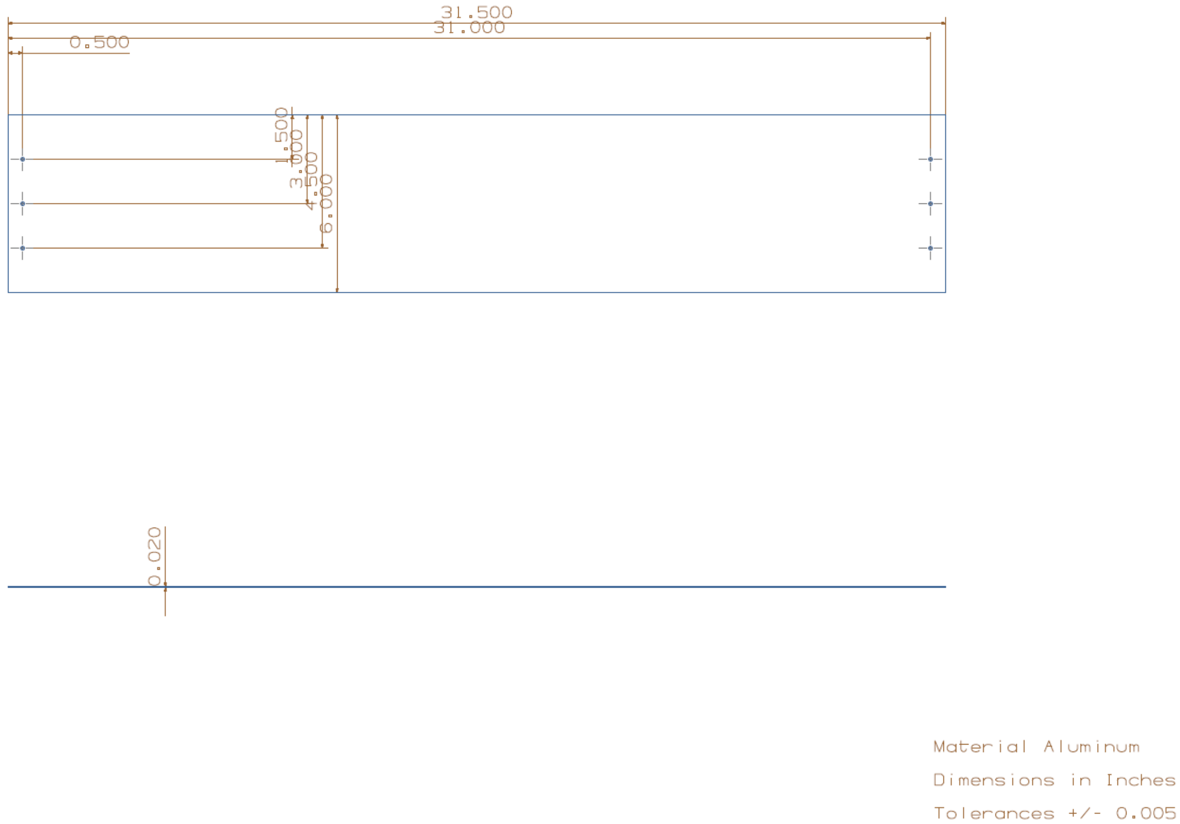
Figure I9: Cross Bar Fabrication Plan

Cross Bar x2

-Band saw tubing within a 1" of desired length

-Square off piece in the mille with 1/2" end mille

Figure I10: Sheet Support

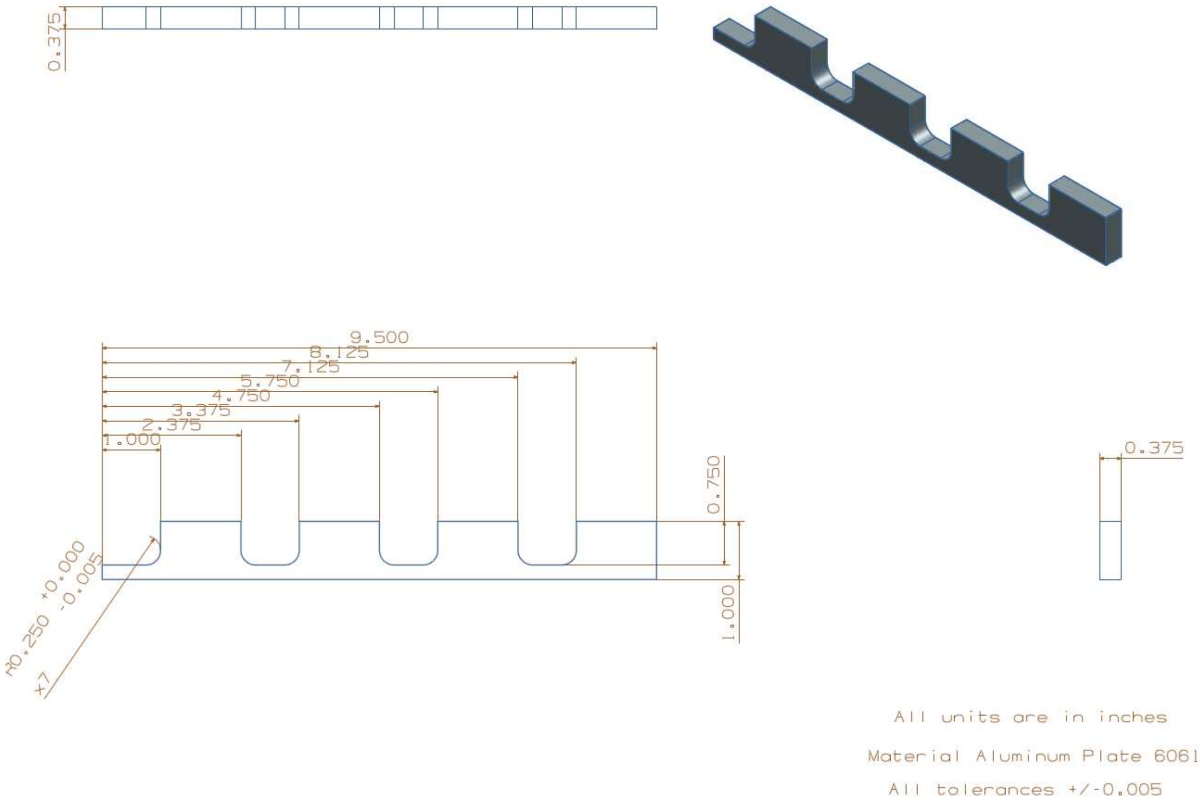


Sheet Support X4

-Shear sheet of steel

-Drill 1/8” holes for rivets

Figure I11: Pegs Fabrication Plan



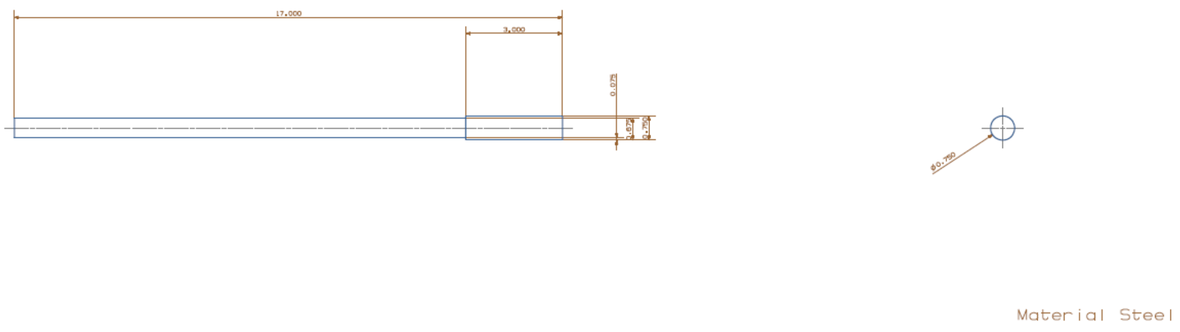
Pegs x2

-Band saw a rough rectangular shape with 1” of the piece dimensions

-Square off piece in the mille using 1/2” end mille

-Create grooves in part with 1/2” end mille

Figure I12: Latch Rod Fabrication Plan



Latch Rod

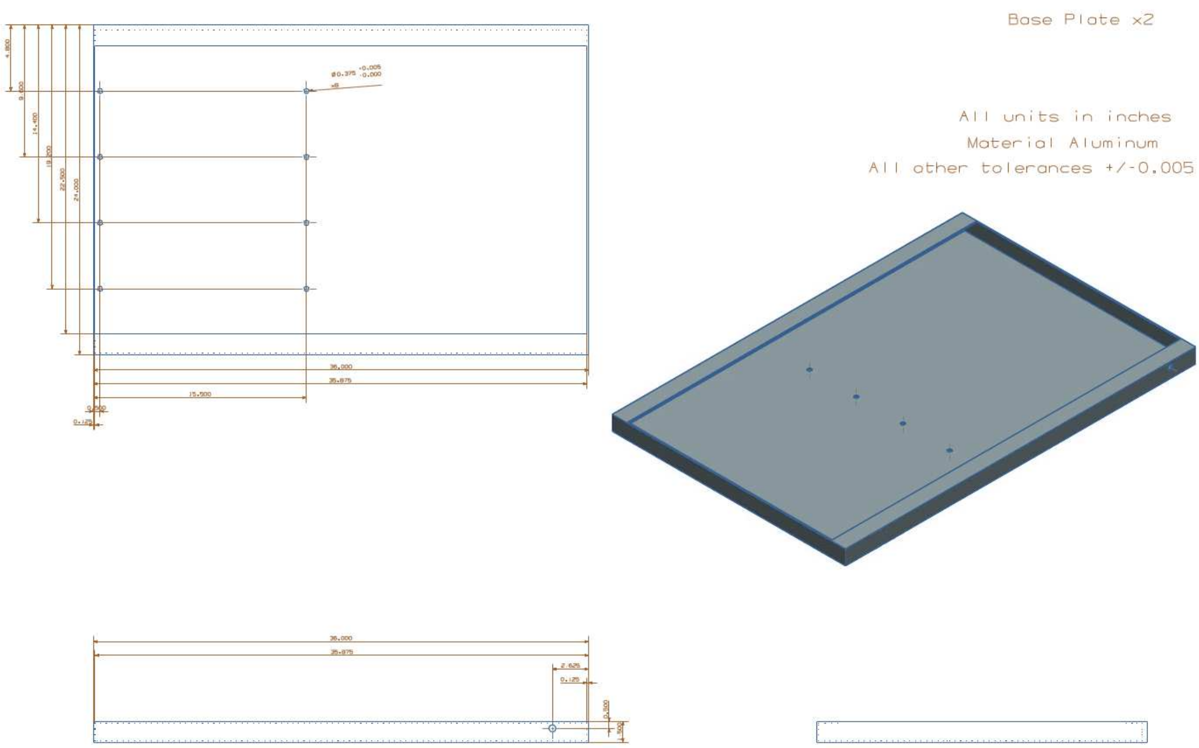
-Bandsaw stock to within 1” of length

-Turn down in the lathe specified amount

-Bandsaw within 1/8” inch

-Faceoff the end in the Lathe

Figure I13: Base Plate Fabrication Plan



Base Plate x2

-Drill holes in pre ordered piece as of now

-Hand drill 3/8" hole with 3/8" drill bit

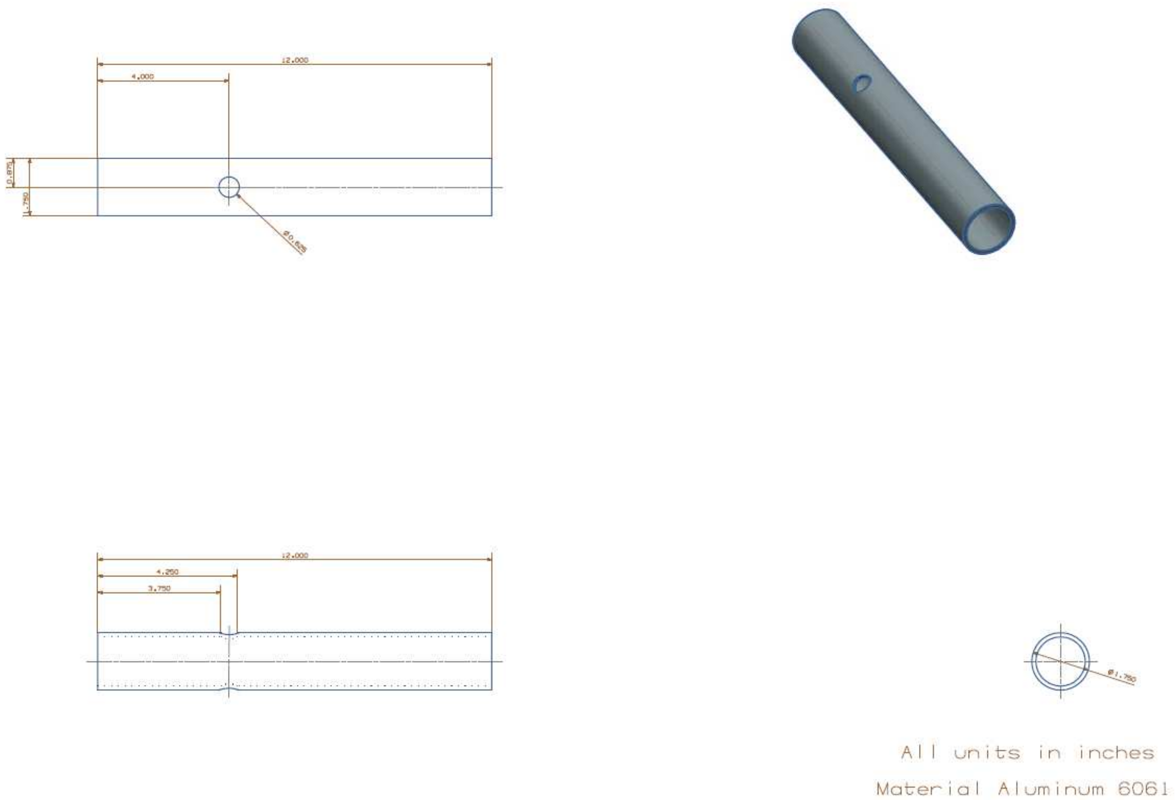
Figure I14: Crossbar for Back Fabrication Plan

Crossbar for back

-Band saw to within 1” of desired length

-Square off piece in the mille with 3/8” end mille

Figure I15: Footrest Fabrication Plan



Foot Rest x2

-Band saw stock to within 1” of part

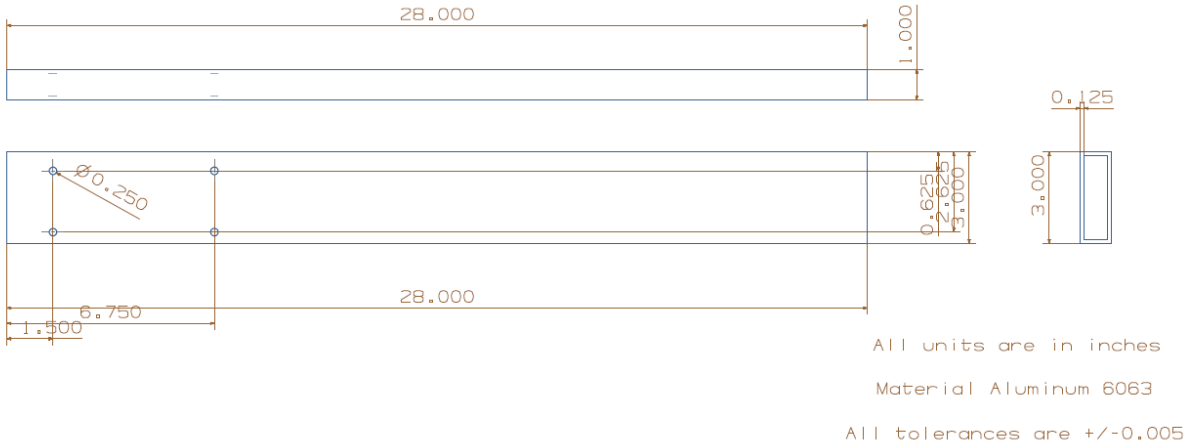
-Square off the part in the mille with 1/2” end mille

-Center drill both holes in the mille

-Drill larger hole with ½” drill bit in mille through the part

-Drill 7/64” hole then ream with 1/8” reamer half way through the diameter of the part

Figure I16: Lower Leg Lengthwise Fabrication Plan

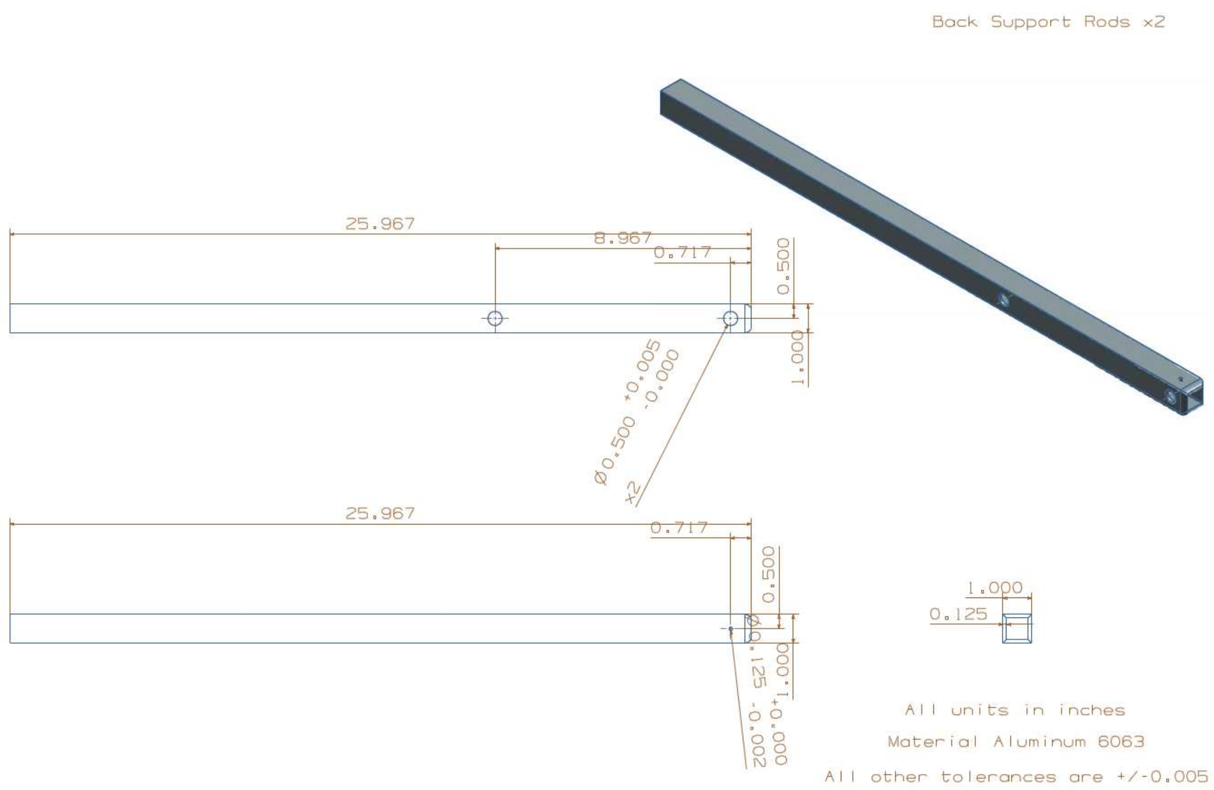


Lower Leg Lengthwise Bar x2

-Band saw tubing within 1/2" of desired length

-Square off the part in the mille with a 1/2" end mille

Figure I17: Back Lengthwise Tubes Fabrication Plan



Back Lengthwise Tubes x2

-Band saw a tube within an 1" of the desired length

-Square off the end in the mille with a 3/8" end mille

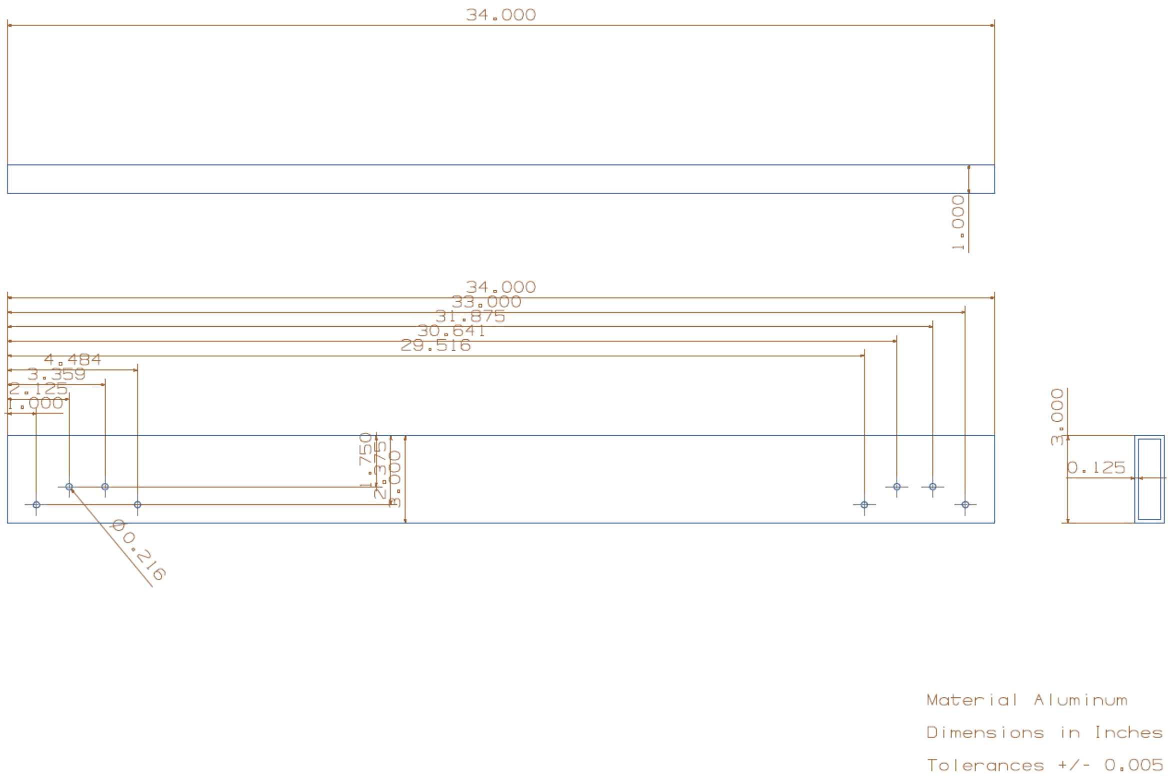
-Center drill all three holes

-Use a ½"drill for the two ½" holes in the mille

-Drill under with a 3/32nd" drill bit in the mille

-Ream a 1/8" inch hole in the 3/32nd inch with a reamer

Figure I18: Hinge Bar Fabrication Plan



Hinge Bar

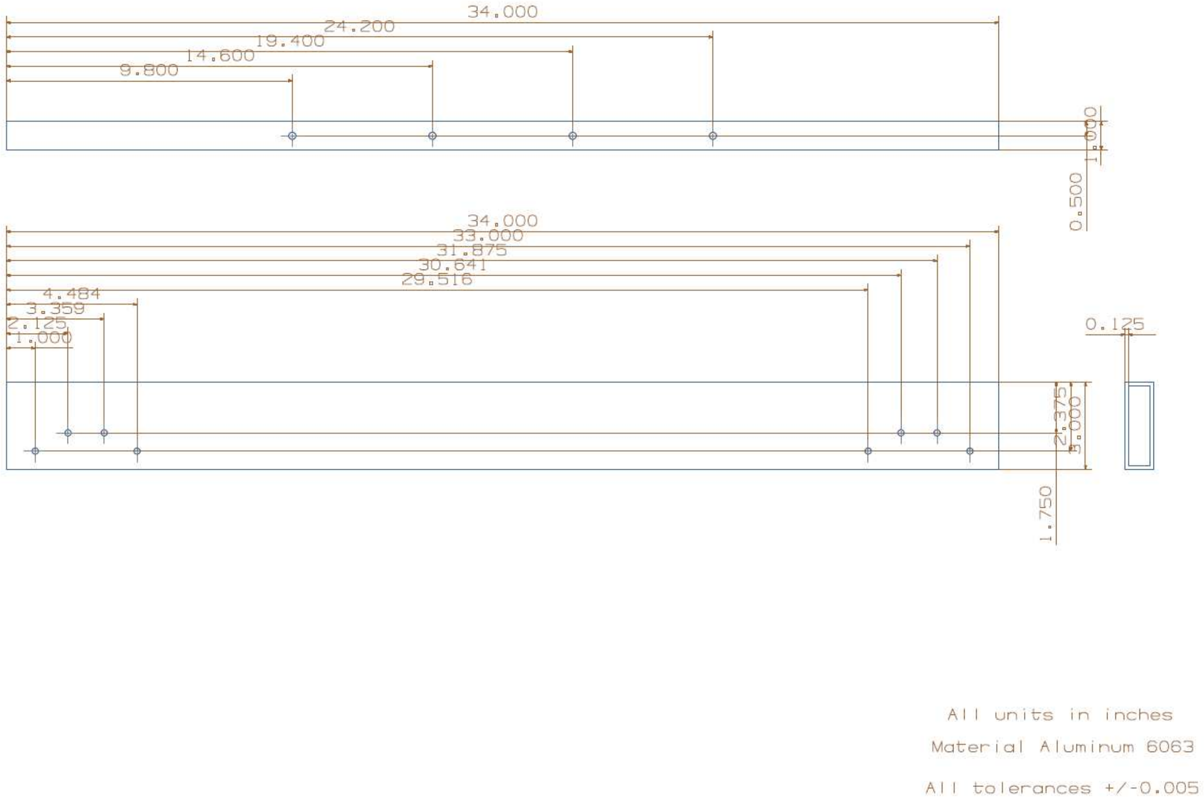
-Band saw the tubing within 1" of the desired length

-Square off the piece in the mille with an 3/8" end mille

-Center drill all four holes in the mille

-Use a ¼" drill bit in the drill press and drill all the way through the tubing

Figure I19: Pelvis Hinge Bar

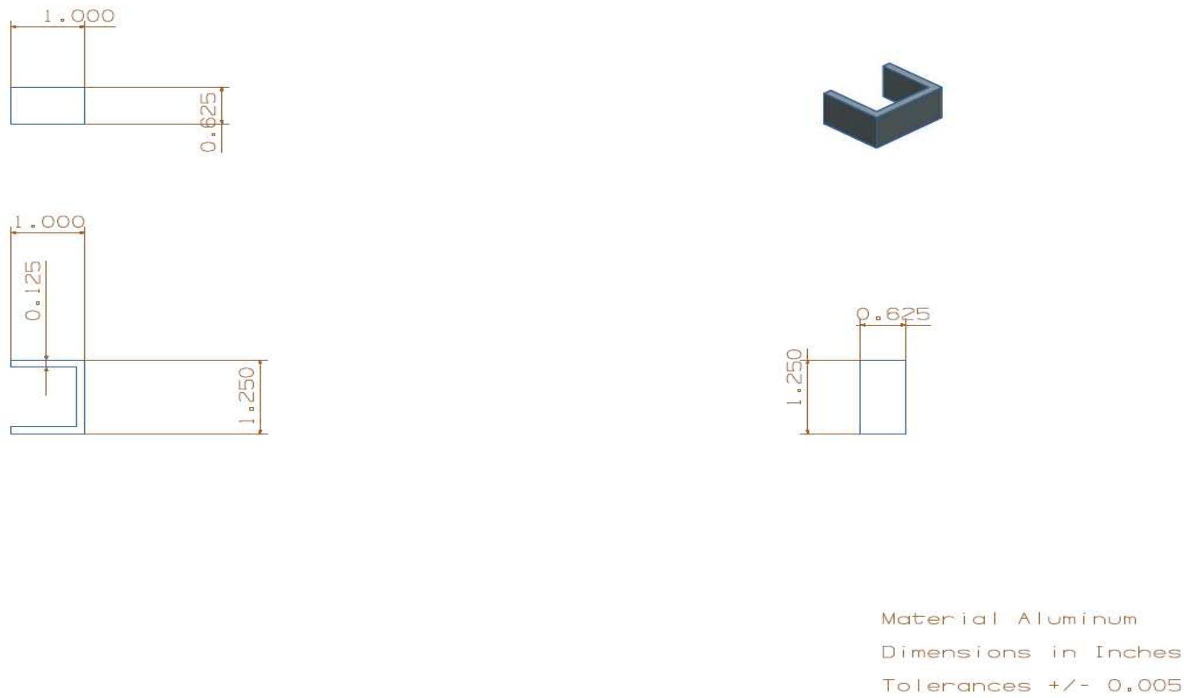


-Bandsaw within ¼” of desired length

-Center drill

-Use ¼” drill bit to make all holes 1600 fps

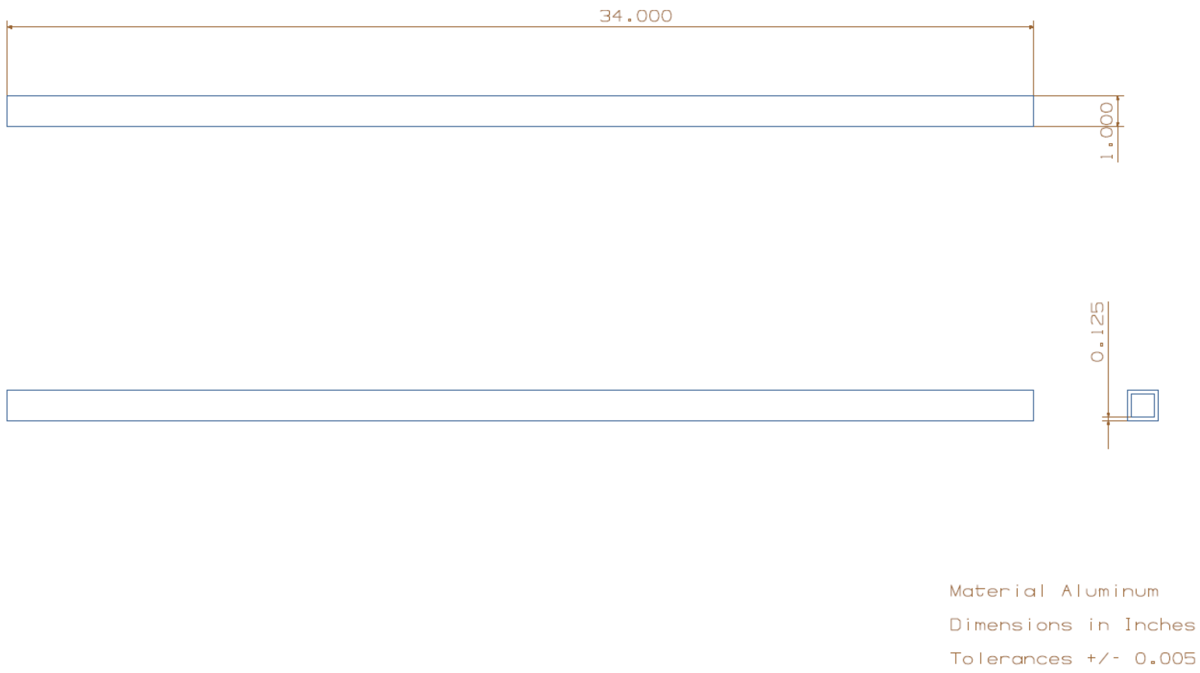
Figure I20: Latch Stopper



-Bandsaw to general shape from tube

-Face with a ½” end mille

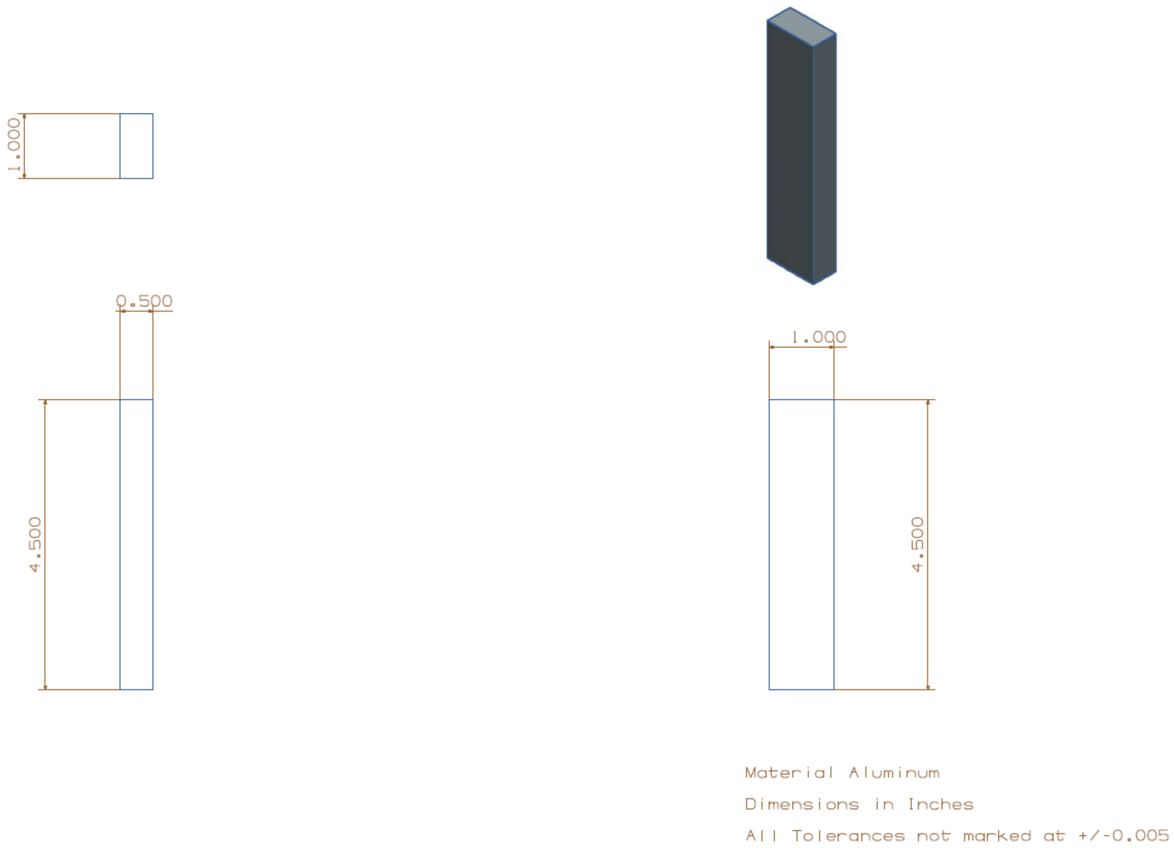
Figure I21: Crossbar Supports



-Bandsaw with ¼" of length

-Face off in mille with ½" end mille at 1600fps

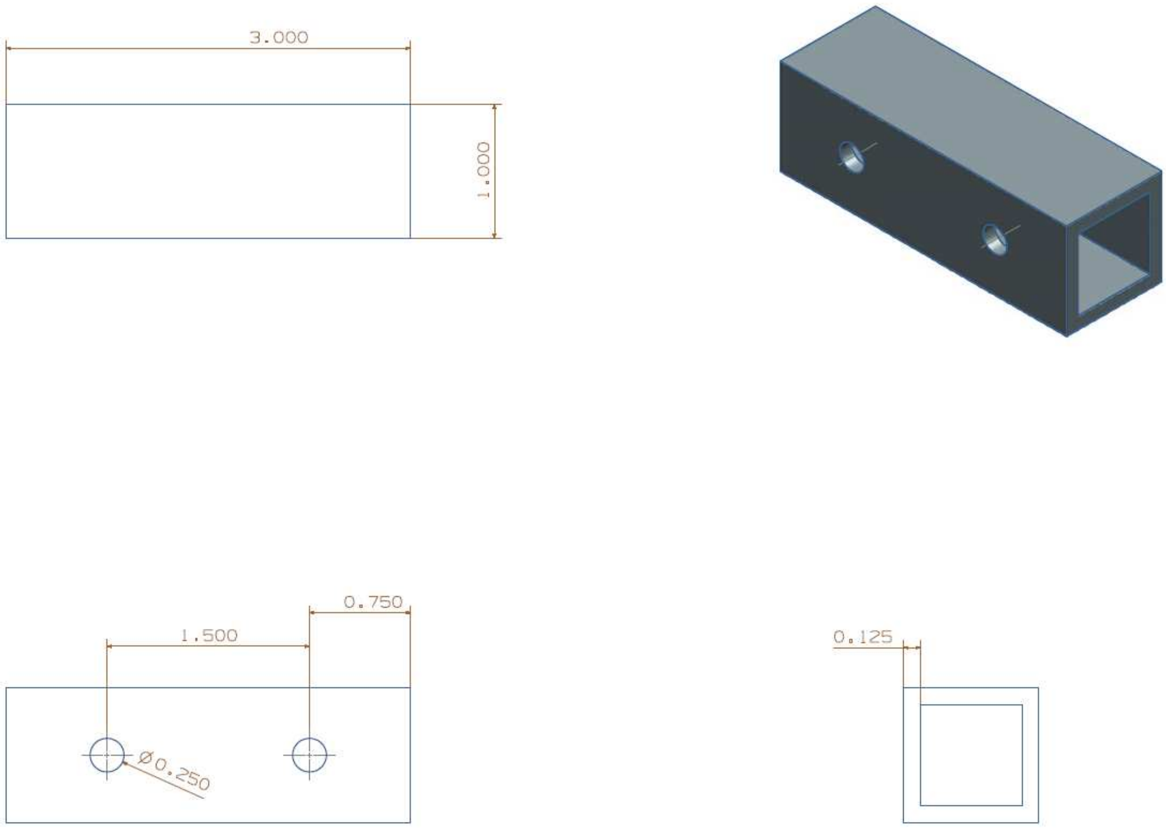
Figure I22: Foot Rest Stopper



-Bandsaw within ¼” of desired dimensions

-Face off in the mille with ½” end mille at 1600fps

Figure I23: Foot Rest Spacer

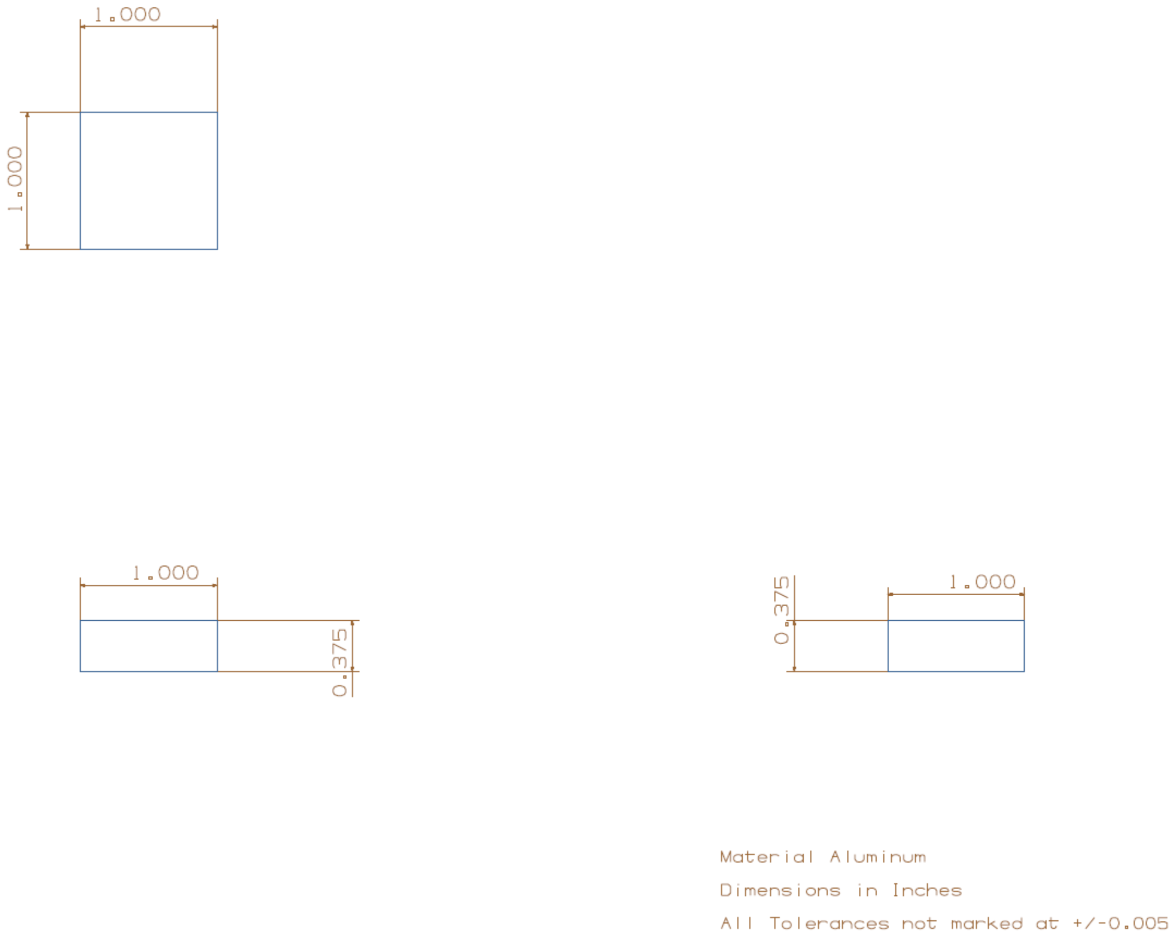


-Bandsaw within ¼” of desired length

-Face off ends in mille with ½” end mille

-Use ¼” drill bit to drill both holes through 1400fps

Figure I24: Foot Rest Stopper Spacer



-Band saw within ¼" of lengths

-Face off in mille with ½" end mille at 1600 fps

Table I1: Bill of Materials

Item no.	Item description	quantity	Price per item	total	Vendor
2.2E+07	3x1 Aluminum rod (+ $5 cutting)	30	4.83	149.9	Alro
2.1E+07	3/4" rod	2	6.23	12.46	Alro
AAA02500	1X1 foot rest tubes	4	2.75	11	Alro
98381A475	Alloy Steel Dowel Pin, 1/8" Diameter, 1" Length	1	13.44	13.44	McMaster
6389K447	Nylon Bearing, Flanged, for 1/2" Shaft Diameter, 5/8" OD, 1" Length	2	5.62	11.24	McMaster
6389K623	Nylon Bearing, Flanged, for 1/2" Shaft Diameter, 5/8" OD, 1/2" Length	1	3.01	3.01	McMaster
6389K624	Nylon Bearing, Flanged, for 3/8" Shaft Diameter, 1/2" OD, 3/4" Length	1	2.98	2.98	McMaster
	5" Twin Size Foam Mattress	1	66	66	Amazon
	36"x80"x7" Vinyl Mattress Cover	1	13	13	Amazon
	1/2" E Clips	10	0.45	4.5	Carpenter Bros
	3" Hinges (Pack of 2)	1	5.99	5.99	Carpenter Bros
	1/2" 3.5" long dia Cap Bolts with nuts	12	1.05	12.6	Carpenter Bros
	Scissor Table	1	169	169	Harbor Freight
	Mechanical Latches	2	20	40	Carpenter Bros
	Total Shipping Charges			16.71	
			Grand Total	531.83	

Table I2: Materials Aquired in Machine Shop

Item	Dimension
Aluminum Sheet support	8"x36"
Larger Sheet Support	12"x31.5"
Peg rods	0.5"x34"
Aluminum Tube	1"x1" , t= 0.125, l= 14'
Steel Latch Bar	0.75" dia. L=17"
Retaining rings	.5/(2)0.357
Bolts	28
Bearings	10

APPENDIX J DESCRIPTION OF ENGINEERING CHANGS SINCE DR3

Comparing the DR 3 Engineering drawings and Final Design Drawings is one way to show changes to our design but a lot of new parts were added in addition

Main Structural Frame
In DR3 our frame was 1x1" tubing throughout but in the prototype and for the final design most of these beams were changed to 3x1" tubes for an increased safety factor and more space for features within the basic frame without adding extra parts.

Back Inclination
Within the back inclination, sheet metal was riveted in strips to add extra support for comfort. This was not originally in DR3 but did make it to our prototype and final design. Bearings were added in several joints to make sure the friction did not make the rotating rods bind up over time. The peg rod increased in diameter for greater stability and a higher safety factor.

Lower Third
Originally in DR3 the hinges were flat when the bed was configured in the supine position but now are closed upon each other and then open to over 90 degrees. The latches on the side of the lower third are much larger than originally intended but ended up being beneficial to human factors. The latch rods are accessible at the foot of the bed for the attendant because of their long length. Extra sheet metal plates were added on top of the support bars for distribution of the weight.

Foot Rests
At first in DR3, the foot rests were locked only with a thumb screw and keyed rod. For the prototype an angle bar stopper was placed beside the foot rest for easy movement by the attendant or patient at the time of delivery without the thumb screws. For the final design, the stoppers increased in size and changed to a rectangular bar over an angle bar. Also bearings were added to the prototype and final design to ensure ease of movement for rotating the foot rests. The foot rests were originally mounted on top of the outer frame but moved to the side with an extra 1" spacer in between.

Lift
The scissor lift was purchased as expected and had hole drilled but was mounted with the foot pump by the back panel instead of the lower third.

Mattress
The mattress for DR3 was so be cut into three separate pieces and mounted on each section separately. For the prototype, only two sections were used combining the back and pelvic section. A cut was made in the back of the mattress to allow bending of the mattress when the back is inclined at higher angles. For our final design we hope to perhaps enclose all separate sections into one vinyl covering.

APPENDIX K DESIGN ANALYSIS ASSIGNMENTS

1. **Material Selection Assignment (Functional Performance)**

The two major components selected are:

a. Bank inclination rod in compression
b. Main frame beam carrying a bending load

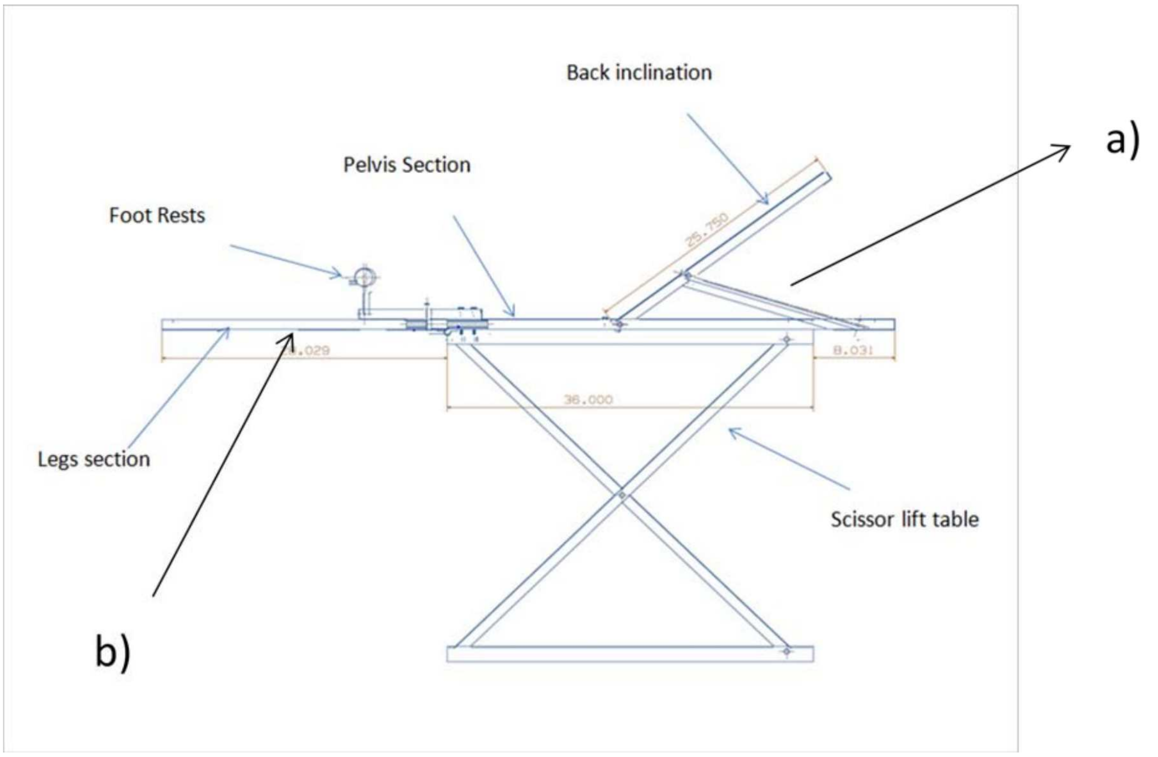


Figure J1.4 Side view of the design

	Function	Objective	Constraints
a. Compression Rod	Rod supposed to carry compressive forces	Minimize mass of the rod	Length *l* is fixed; rod should not yield in compressive force F
b. Bending beam	Beam in bending	Minimize the mass of the beam	Length *l* is fixed; Support bending load F without failing by yield or fracture.

Material Indices:

a. Compression Rod:
   m = AL

   $\frac{F}{A} \leq \sigma_f$

   Where σ_f is the failure strength.

   Eliminating A, we get, $m \geq (F)(l)(\frac{\rho}{\sigma_f})$

   The material index M= $\frac{\sigma_f}{\rho}$

b. Bending Beam:
   The failure load of a beam is : $F_f = C_2 \frac{I\,\sigma_f}{y_m\,l}$

   Where y_m is the distance between the neutral axis of the beam and its outer filament; C_2 is a constant based on the load distribution.

   I= $b^4/12$

   Combining with the mass equation we get, $\left(\frac{6}{C_2}\frac{F_f}{\ell^2}\right)^{2/3}\ell^3\left[\frac{\rho}{\sigma_y^{2/3}}\right] \quad m =$

   The material index here would be $M = \frac{\sigma_f^{\frac{3}{2}}}{\rho}$

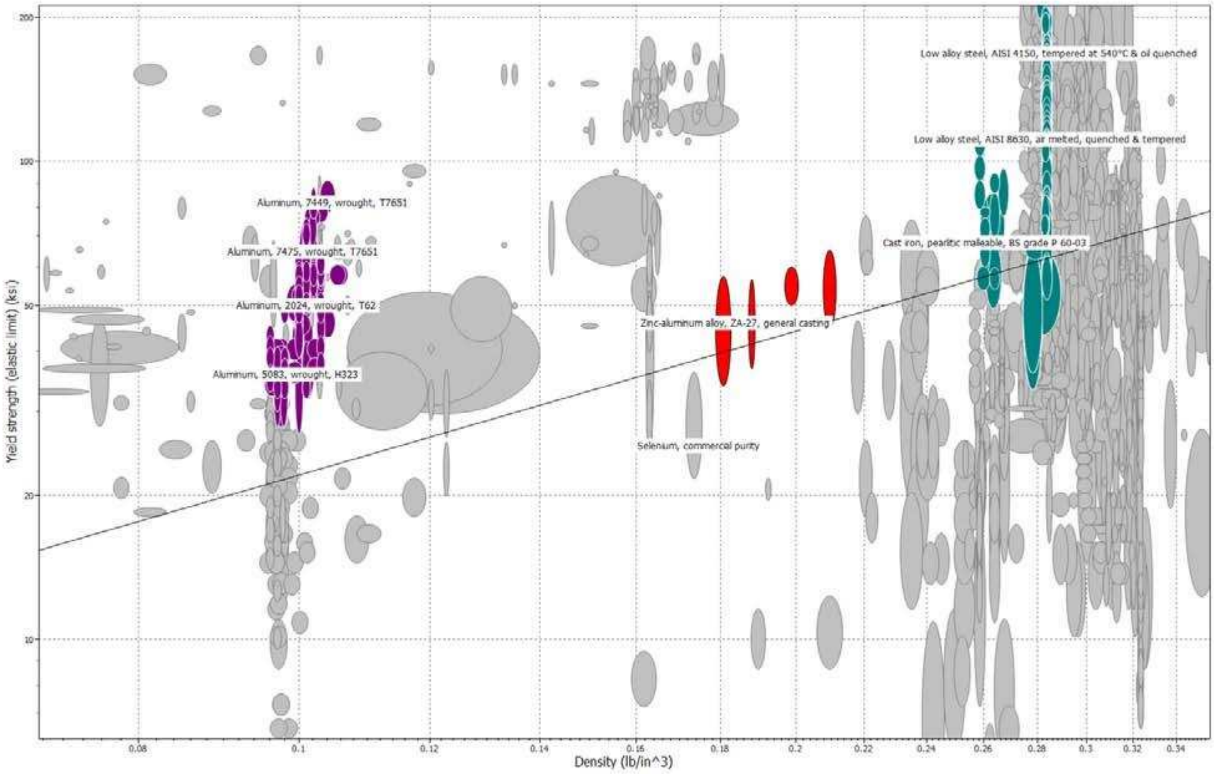
Materials were down selected using the CES software. We plotted a graph of yield strength vs density and then added two lines of slopes 1 and 0.66 based on our material indices and the top five choices for compression rod were different kinds of low allow steel. The list below includes the top choice and then some other kinds of metals that passed the test:

- Low alloy steel, AISI 9255, tempered at 205°C & oil quenched and other low alloy steel
- Aluminum, 7055, wrought, T77511
- Carbon steel, AISI 1340, tempered at 425°C & oil quenched
- Aluminum 6063, wrought, T6

We finally selected Aluminum 6063 due to three reasons. Firstly, Aluminum was the least dense metal that passed our yield strength criteria (can be seen in the graph below) and we want to design this device as light as possible. Secondly, Aluminum is anticorrosive and would be able to withstand the bleach used in the hospital settings. Thirdly, from our field scoping experience in Ghana, we determined that Aluminum 6063 is readily available in the local market and since we want this device to be produced with locally available materials Aluminum 6063 emerged as the top choice.

The reason to use the same material for both the bending and compression rod is that these components will be welded together and it is not feasible to weld two different materials together. We were again constrained by the materials available in Ghana and preferred to use the same kind of material for different parts to decrease complexity for maintenance reasons.

Graph: *Results from CES Software. The purple colored region on the left (least dense area corresponds to Aluminum)*



2. **Material Selection Assignment (Environmental Performance)**

Two materials that were chosen through CES were both Aluminum. Therefore for SimaPro, we've selected, "Aluminum, secondary, ingot, at plant" as our first material, referred to as Aluminum 1 and "Aluminum, secondary, shape casted," as our second material, referred to as Aluminum 2. All results of this section show very high numbers. This is because our device is large in scale and requires so much material. The mass of material that was inputted was about 50kg.

Below in Figure J2.1 we calculate the total mass of air emissions, water emissions, and use of raw materials comparison between the two aluminum choices. We did not have any results for "waste," and so only have three columns. Across all categories, Aluminum 2 gives off more mass.

Figure J2.1: Graph of Total Mass Comparison

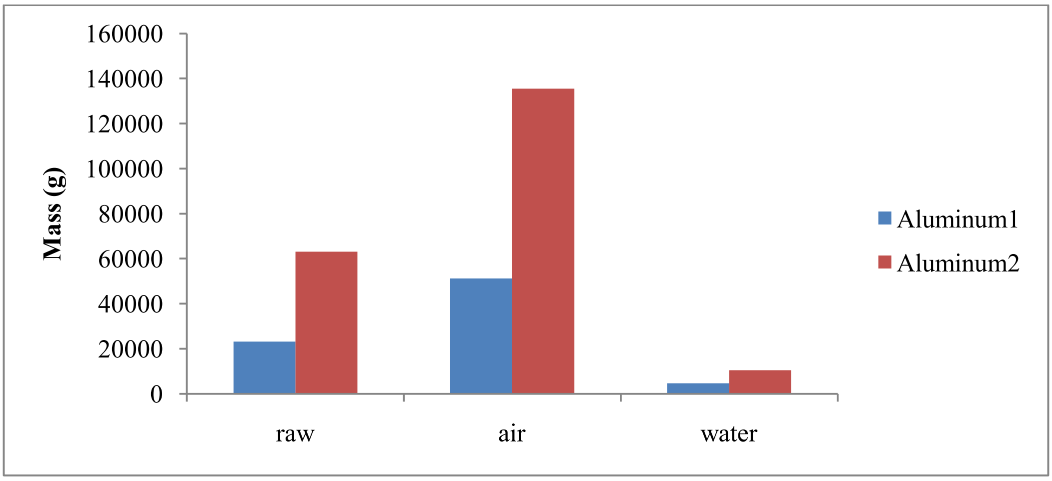
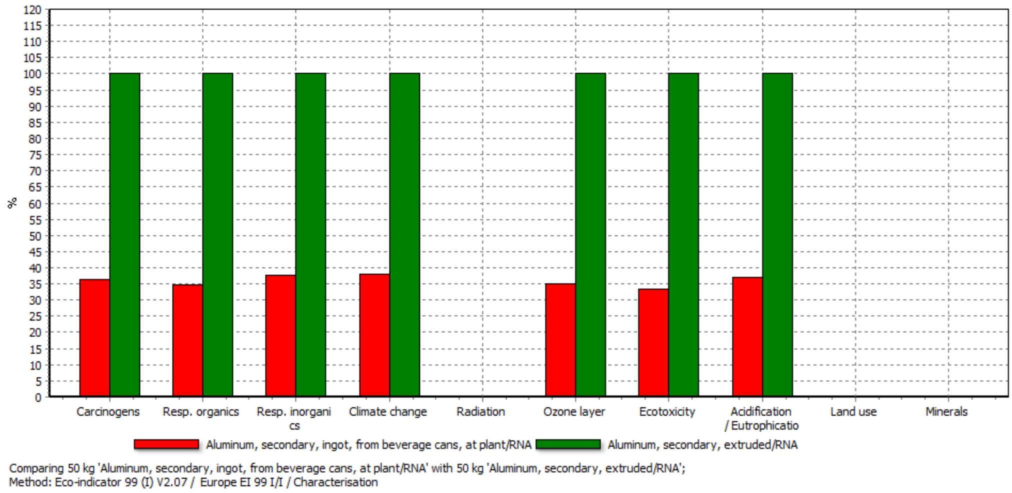
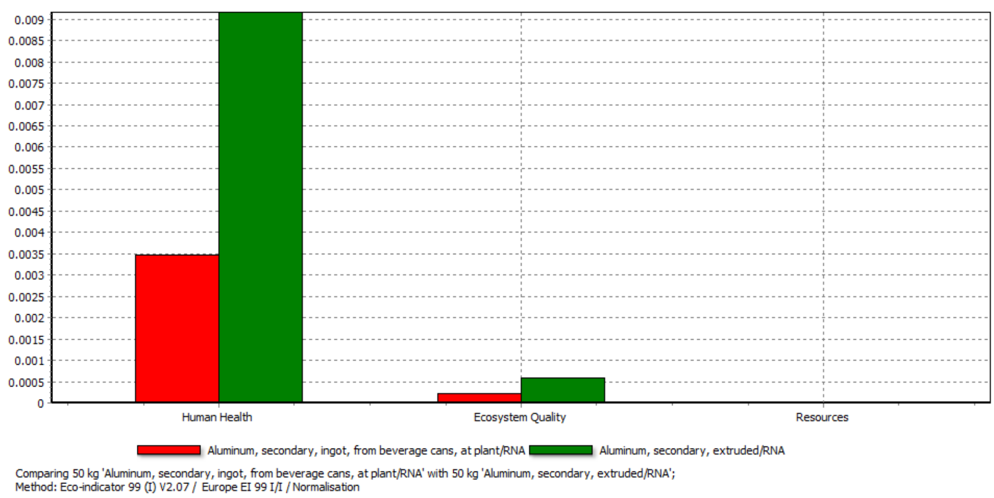


Figure J2.2: Comparison of Material Performance in EI99 Impact Categories



For all categories of hazard emission, Aluminum 2 is more harmful than Aluminum 1. Aluminum 1 is only about 35% as toxic as Aluminum 2. These catagories show the effect of using these materials on human health and the disability adjusted life year (DALY) which measures the overall disease burden. All categories are equally impacted.

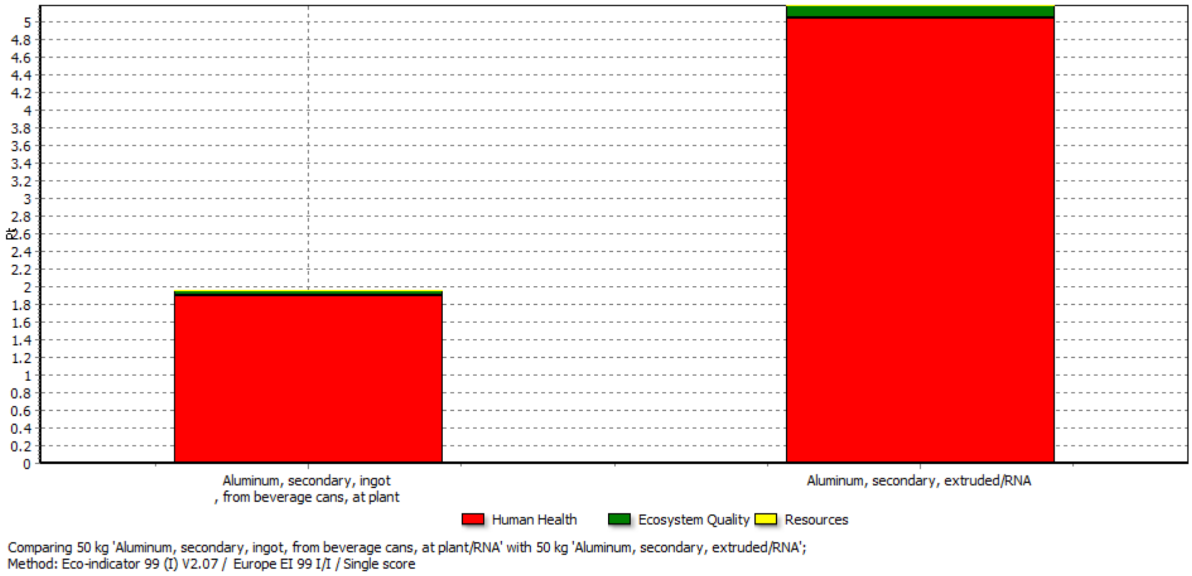
Figure J2.3 Comparison of Material Performance in Normalized



As with the previous objectives, it seems as though Aluminum 2 is more harmful to the environment than Aluminum 1. For human health and DALY, Aluminum 2 causes a much higher hazard than Aluminum 1. Aluminum 1 only causes 35% of the DALY than Aluminum2. The impact to ecosystem quality was relatively low compared to that of human health. Again, there seemed to have been fewer categories outputted with this comparison. Resource/megajoules of surplus are essentially nothing for both materials meaning the average

Eurpean person does not contribute to wasteful surplus of energy over one year due to our materials.

Figure J2.4: Comparison of Material Performance



The impact to human health is drastic compared to that of ecosystem quality and as already discovered Aluminum 2 is more harmful than Aluminum 1.

Since Aluminum would be used regardless, it would be a luxury to use the material that is less negatively impactful to the environment. The full cycle would not make one more important than the other since they are essentially the same core material.

I think further exploration of Simapro and other materials would be worthwhile if we were to take this prototype further, which we are interested in as we move into the next semester of design. Because our target end-users are low-resource settings, and our eventual goal would be to manufacture in country, I do not know if it would be possible to have the availability of using the most “ideal” material.

3. **Manufacturing Process Selection Assignment**

To determine a real-world production volume we will have to make some assumptions.

Assumptions:

- The number of deliveries that can take place in a day on one single bed is equal to 1.
- On an average 35% of all deliveries take place in healthcare facilities, where our device can be implemented. * (In Ghana it is 58% and in Bangladesh it is 9%)
- New beds will be added to meet the ideal requirements and existing beds will be replaced in the next 10 years.

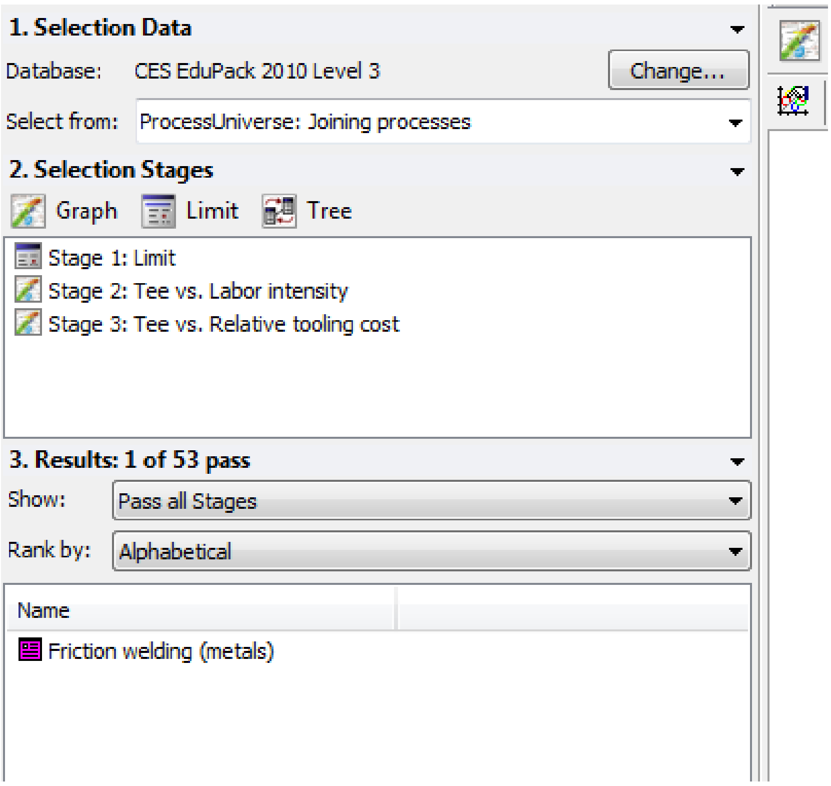
Country or Area	**Total deliveries**	**Estimated daily deliveries**	**% Facility births**	**Beds needed**
Africa	35,318,000	98,106	35%*	**34,337**
Asia	68,409,000	190,025	35%*	**66,509**
Latin America and Caribbean	10,768,000	29,911	35%*	**10,469**

Based on these assumptions we get a total of approximately 110,000 that will be needed in Africa, Asia, Latin America and Caribbean combined (only developing world considered since our device is for low resource settings). Now we will assume that due to other competitors and other factors, we will have a 25% share in the entire market. This will require us to make 27,500 beds.

For the manufacturing process selection we will assess the best method for cutting the metal rods for the lower third of the bed and the best method to assemble the rods used for the back inclination. The material for these rods were derived from the materials selection assignment and the top two materials were Aluminum 6063, wrought, T6 and Low alloy steel, AISI 9255.

For cutting the best method suggested by CES is Abrasive jet machining (AJM). The equipment for AJM is inexpensive with low tooling costs. It is a labor intensive process but given that our device has to be made in developing countries, labor costs should be less and it is more important to keep the equipment costs low. This is a slow process but cutting of metal will not be a rate defining process in our device manufacturing so it will not have an effect on overall rate of production. The economic batch size for this machine ranges from 1 to 100,000, which is good since we can use it to manufacture a batch of virtually any size depending on the demand of our product. Since our device will be a long term purchase for any institution, they will not replace it fast and our manufacturing method should be feasible for making small sized batches.

For joining metals together for the back inclination as well the main frame the best method suggested by CES is friction welding. This process has a low relative tooling cost and can be completely automated. This is also the best way of joining dissimilar metals together and gives us the choice to have different metals in different sections of the device to reduce costs. The tolerances are low and the welding can take all kinds of loads. Below is a snapshot from the CES process selection software:



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